

Message

From: Berger, Tom C. [Berger@khlaw.com]
Sent: 2/12/2020 2:12:41 AM
To: Schweer, Greg [Schweer.Greg@epa.gov]
Subject: Re: PMN backlog

Anything I could get by noon Wednesday would be helpful but of course understand if you can't respond.

Thanks as always - Tom

On Feb 11, 2020, at 9:57 AM, Berger, Tom C. <Berger@khlaw.com> wrote:

Hi Greg –

I hope that all is well!

During Keller and Heckman's next monthly "30/30" webinar, which is tomorrow, I will be talking about how the regulated community should not be afraid of the PMN section 5 process. I was going to mention faster reviews and reduced PMN backlog. Can you give me and very general information/stats on these topics? The last figures I have are from last October ("278 PMNs"). I will or will not give attribution for any information you provide as you indicate.

Thanks much –
Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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Message

From: Berger, Tom C. [Berger@khlaw.com]
Sent: 2/11/2020 2:58:28 PM
To: Schweer, Greg [Schweer.Greg@epa.gov]
Subject: PMN backlog

Hi Greg –

I hope that all is well!

During Keller and Heckman's next monthly "30/30" webinar, which is tomorrow, I will be talking about how the regulated community should not be afraid of the PMN section 5 process. I was going to mention faster reviews and reduced PMN backlog. Can you give me any very general information/stats on these topics? The last figures I have are from last October ("278 PMNs"). I will or will not give attribution for any information you provide as you indicate.

Thanks much –
Tom

Thomas C. Berger
Partner
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Message

From: Bauer, Jeff [Bauer.Jeff@epa.gov]
Sent: 6/16/2020 12:50:13 PM
To: Berger, Tom C. [Berger@khlaw.com]
CC: Price, Amanda [price@khlaw.com]; Schweer, Greg [Schweer.Greg@epa.gov]; Daniels, Rhys G. [daniels@khlaw.com]; Edelstein, Rebecca [Edelstein.Rebecca@epa.gov]; Alwood, Jim [Alwood.Jim@epa.gov]; Moss, Kenneth [Moss.Kenneth@epa.gov]
Subject: RE: **Ex. 4 CBI**

Tom,

How about I try and set it up for July 1st. in the afternoon.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

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1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Monday, June 15, 2020 4:05 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Alwood, Jim <Alwood.Jim@epa.gov>; Moss, Kenneth <Moss.Kenneth@epa.gov>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope you had a great weekend.

We had our call on May 27 and the submitter is inquiring as to status. The questions/topics at issue are:

- (1) Scheduling a call on the 5(e)/SNUR case at issue; and
- (2) The issue of whether when a section 5(e) order is modified or revoked, does EPA “automatically” seek to amend or revoke the corresponding SNUR accordingly?

Thanks again - Tom

From: Berger, Tom C.
Sent: Tuesday, June 9, 2020 12:53 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; alwood.jim@epa.gov; Moss, Kenneth <Moss.Kenneth@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>
Subject: RE: **Ex. 4 CBI**

Hi folks –

Sorry to be a pest but just checking in again.

Thanks again - Tom

From: Berger, Tom C.

Sent: Thursday, June 4, 2020 10:12 AM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>; alwood.jim@epa.gov; Moss, Kenneth <Moss.Kenneth@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>

Subject: RE: **Ex. 4 CBI**

Hi folks –

Just checking in on the below two items.

Thanks again - Tom

From: Berger, Tom C.

Sent: Monday, June 1, 2020 5:55 PM

To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>; 'alwood.jim@epa.gov' <alwood.jim@epa.gov>; 'Moss, Kenneth' <Moss.Kenneth@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; 'Schweer, Greg' <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; 'Edelstein, Rebecca' <Edelstein.Rebecca@epa.gov>

Subject: RE: **Ex. 4 CBI**

Hi folks –

I hope you had a great weekend!

Just checking in on:

- (1) Scheduling a call on the 5(e)/SNUR case at issue; and
- (2) The issue of whether when a section 5(e) order is modified or revoked, does EPA “automatically” seek to amend or revoke the corresponding SNUR accordingly?

Thanks all - Tom

From: Berger, Tom C.

Sent: Thursday, May 28, 2020 12:23 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; alwood.jim@epa.gov; Moss, Kenneth <Moss.Kenneth@epa.gov>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just following up on this.

Also (and I am cc'ing Jim Alwood and Ken Moss), per our discussions, if and when the section 5(e) order at issue here is modified (or perhaps even revoked), would EPA "automatically" seek to amend or revoke the corresponding SNUR accordingly? As we discussed, as there are dozens of processors interested in the "new use" being sought, filing one or more SNUNs is not workable. However, the PMN submitter/manufacture could submit a request to amend or revoke the SNUR under 721.185(b)(1).

Thanks again – Tom

From: Berger, Tom C.
Sent: Wednesday, May 27, 2020 2:57 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Thanks for taking the time to meet with us. Should we pencil in a time two weeks from now (i.e., June 9 or June 11) for our next call?

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, May 13, 2020 1:32 PM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom,

I sent a meeting request to you three for May 27th at 2 p.m. to give a status update as requested.

Thanks

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

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Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Wednesday, May 13, 2020 12:53 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just seeing if it makes sense to set up a conference call in a week or two.

Thanks much again - Tom

From: Berger, Tom C.

Sent: Friday, May 8, 2020 11:14 AM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Jeff/Greg – thanks again.

Can/should we schedule a conference call with the submitter in a week or two?

Happy Friday!

Tom

From: Berger, Tom C.

Sent: Thursday, May 7, 2020 4:17 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: Re: **Ex. 4 CBI**

Jeff - thanks much.

Tom

On May 7, 2020, at 4:03 PM, Bauer, Jeff <Bauer.Jeff@epa.gov> wrote:

Tom, I hope you hanging in there as well, I have an email out to see if I can get a status update on the Assessor and to address you questions sent into CDX for a meeting.

Jeff

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
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From: Berger, Tom C. <Berger@khlaw.com>
Sent: Thursday, May 07, 2020 1:57 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: Ex. 4 CBI

Hi Jeff – Just touching base as the submitter has requested a status update.

Thanks again - Tom

From: Berger, Tom C.
Sent: Tuesday, May 5, 2020 11:56 AM
To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; 'Schweer, Greg' <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: Ex. 4 CBI

Hi Jeff – Just checking in on this – thanks - Tom

From: Berger, Tom C.
Sent: Wednesday, April 29, 2020 11:12 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: Ex. 4 CBI

Hi Jeff –

I just thought I would check in on this and see if the Agency needs any additional information.

Thanks again and best regards,
Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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From: Berger, Tom C.
Sent: Thursday, April 23, 2020 7:13 PM
To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Jeff - thanks much.

Your recent voicemail and follow-up email indicated that the EPA Chemist has evaluated the **Ex. 4 CBI** study" on **Ex. 4 CBI**, but that the reviewer did have a few questions and comments:

Ex. 4 CBI

To specifically answer the Chemist's questions:

Ex. 4 CBI

Ex. 4 CBI

* * *

We trust that you find this information useful in resolved all outstanding issues. As always, if you have any questions please do not hesitate to contact us.

Best regards,
Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Tuesday, April 21, 2020 5:17 PM
To: Daniels, Rhys G. <daniels@khlaw.com>; Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: **Ex. 4 CBI**

I am moving forward with the review based on the information I have on the two studies, I wanted to share with you her comments on the test. **Ex. 4 CBI**

Ex. 4 CBI RAD has the information and I am trying to get them to do the risk assessment based on **Ex. 4 CBI**

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
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<http://www.epa.gov/oppt/newchemicals/>

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From: Daniels, Rhys G. <daniels@khlaw.com>
Sent: Tuesday, April 21, 2020 4:58 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Berger, Tom C. <Berger@khlaw.com>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>

Subject: RE: **Ex. 4 CBI**

Jeff,

As always, we hope that all is well.

Per your recent voicemail and follow-up email concerning the **Ex. 4 CBI** case, we understand that the chemist has two questions concerning the **Ex. 4 CBI**

Ex. 4 CBI

Thanks in advance for your response.

Rhys G. Daniels, Ph.D.
Staff Scientist

tel: +1 202.434.4270 | fax: +1 202.434.4646 | daniels@khlaw.com
1001 G Street NW, Suite 500 West | Washington, DC 20001



From: Bauer, Jeff <Bauer.Jeff@epa.gov>

Sent: Thursday, April 16, 2020 1:02 PM

To: Berger, Tom C. <Berger@khlaw.com>

Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>

Subject: RE: **Ex. 4 CBI**

Tom,

The chemist sent me a memo **Ex. 4 CBI** and they had two questions, I called and left you a message today **Ex. 4 CBI** I sent RAD a request last week to update the HH assessment **Ex. 4 CBI** as in my April 4, 2020 email to you. I have two emails into RAD on this case and will try an update you again in a week or so. I requested RAD set up a date with me to have a meeting to discuss how to proceed with this PMN.

Thanks
Jeff

Jeff Bauer - Program Manager

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From: Berger, Tom C. <Berger@khlaw.com>
Sent: Thursday, April 16, 2020 12:28 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope that all is well.

Just checking in re status update. A non-CBI-containing email from you would probably be the best (if needed at some later time we can use EPA's new CBI via email authorization form if the submitter agrees).

Thanks again – Tom

From: Berger, Tom C.
Sent: Wednesday, April 8, 2020 11:06 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Jeff – thanks much for the update. Hope you and all at EPA are staying safe.

Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, April 8, 2020 11:03 AM
To: Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom,

Ex. 4 CBI

I will follow up with you next wed with a status update.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
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From: Berger, Tom C. <Berger@khlaw.com>
Sent: Wednesday, April 08, 2020 10:48 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Greg –

I was just going through my to-do list and thought I would circle back on these two cases. I hope everyone is hanging in there.

Thanks again – Tom

From: Berger, Tom C.
Sent: Monday, March 30, 2020 3:46 PM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Greg / all – completely understood – thank you so much.

Tom

From: Schweer, Greg <Schweer.Greg@epa.gov>
Sent: Monday, March 30, 2020 3:42 PM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>
Subject: RE: **Ex. 4 CBI**

Hi Tom.

I am not ignoring you. I did check with Jeff Bauer early last week on this case. He filled me in on the requests he had made of RAD to review submitted test data and your request for a meeting. However, believe it or not, we have been having issues reliably being able to access our CBI-secure LAN. This hampers our ability to efficiently complete work. I will check on the status of your case as soon as I can.

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Monday, March 30, 2020 11:51 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Greg –

Hope all is well.

Just thought I would check in with you on the **Ex. 4 CBI** LVEA (Lauren Davis) and **Ex. 4 CBI** **Ex. 4 CBI** with Jeff Bauer.

Thanks all always - Tom

From: Berger, Tom C.
Sent: Tuesday, March 24, 2020 11:12 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Greg – thanks so much as always. I also have an LVE with Lauren Davis: **Ex. 4 CBI** **Ex. 4 CBI** is held up in the process. Lauren has been responsive but the case has stalled (again, however, I understand the challenges you are facing).

These are my two “priority” cases.

Tom

From: Schweer, Greg <Schweer.Greg@epa.gov>
Sent: Tuesday, March 24, 2020 11:07 AM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: Re: **Ex. 4 CBI**

Tom,

Yes, things are a bit crazy. I will check into the case status today or tomorrow.

Sent from my iPhone

On Mar 24, 2020, at 10:48 AM, Berger, Tom C. <Berger@khlaw.com> wrote:

Hi Greg –

Obviously things are crazy and I don't want to push Jeff too hard but no response from Jeff on this case for a month.

Hang in there....

Tom

From: Berger, Tom C.
Sent: Monday, March 23, 2020 6:22 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies – just want to make sure you are getting these emails. Understand if there are delays.

Tom

From: Berger, Tom C.
Sent: Thursday, March 19, 2020 5:22 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff – checking in again – thanks - Tom

From: Berger, Tom C.
Sent: Monday, March 16, 2020 1:40 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I know things are crazy but checking in again – thanks - Tom

From: Berger, Tom C.
Sent: Wednesday, March 11, 2020 3:43 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Checking in again - thanks

From: Berger, Tom C.
Sent: Friday, March 6, 2020 1:33 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

The submitter is quite anxious – can we touch base next week?

Thanks much - Tom

From: Berger, Tom C.
Sent: Tuesday, February 25, 2020 9:08 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just checking in on this – thanks - Tom

From: Berger, Tom C.
Sent: Thursday, February 20, 2020 12:18 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope that all is well.

Per our discussions, the submitter has modified the questions to focus on toxicity/risk issues and submitted them via CDX yesterday. Can we start looking at conference call dates the week of March 9?

Thanks and best regards,
Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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From: Berger, Tom C.
Sent: Wednesday, January 29, 2020 11:41 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies we keep playing phone tag – can we discuss how to convert the below questions into questions that would be acceptable to RAD so we can schedule a call with you and RAD? Your voicemail suggested the below are more legal/regulatory than risk-based questions. We still need the below questions answered – perhaps we tee up the more scientific ones for RAD then have the call to address both types of questions. The submitter is under growing commercial pressure.

Thanks much again - Tom

From: Berger, Tom C.
Sent: Monday, January 20, 2020 3:50 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies that we could not connect last week. Let's try to touch base tomorrow (Tuesday) if possible to discuss how to move this forward.

Thanks again – Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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From: Berger, Tom C.
Sent: Monday, January 13, 2020 2:50 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**
Importance: High

Hi Jeff –

Following is the list of questions we are considering submitting through CDX. Please let me know if these look ok.

Thanks again and best regards,
Tom

* * *

*(1) Based on review of the submitted physical-chemical properties test data, does EPA now agree that use **Ex. 4 CBI** as described in the PMN poses no unreasonable risk of injury and so plans to revoke the consent order?*

(2) If so, what is the process for revoking the current consent order? Does the submitter now need to request that EPA revoke the order, or will EPA itself initiate revocation? What is the expected timing for revocation? How would EPA communicate such revocation?

(3) How would revocation of the consent order impact the final SNUR for the subject substance?

(4) Would a SNUN be a more expedient approach?

* * *

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, January 8, 2020 8:56 AM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom, I am expecting information from the engineer today or tomorrow on the **Ex. 4 CBI** test, I left you a message. There is a new procedure for us to set up meeting with RAD. I am to have the submitter send in a list of questions for RAD, they will assign someone up there as a Lead person who has two weeks and will set a date for when we can have a meeting. This may be our best route to other than just me bugging them to get things done. There were a series of emails on this case last week but now everyone is back from the holidays I am trying to get this case moving again.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Tuesday, January 07, 2020 4:16 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope you had a great holiday! The client was wondering if we could have a conference call on this, this week or next. Please advise.

Thanks much – Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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From: Berger, Tom C.
Sent: Tuesday, December 10, 2019 2:10 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just checking back in – thanks - Tom

From: Berger, Tom C.
Sent: Thursday, December 5, 2019 9:46 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

When we spoke before Thanksgiving (I hope you had a great one!) you indicated that the reports were being reviewed and that I should reach out to you in early December.

Is there any update?

Thanks much and best regards – Tom

Thomas C. Berger
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tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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From: Berger, Tom C.
Sent: Monday, November 18, 2019 1:17 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

The PMN submitter asked me to reach out to you to see if we can schedule a conference call (including EPA, K&H, and the submitter) on this case re status and pathforward.

Thanks - Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Friday, March 29, 2019 5:43 PM
To: Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom,
I set the meeting up for Wednesday April 3, at 11 am. RAD has accepted the invitation for that time.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Bauer, Jeff
Sent: Tuesday, March 26, 2019 11:37 AM
To: 'Berger, Tom C.' <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom, I left you a voice message, I am seeing what time it best for RAD to be part of the call.

Jeff Bauer - Program Manager

United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Tuesday, March 26, 2019 11:30 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi folks –

Just thought I would check in with you on this.

Thanks again - Tom

From: Berger, Tom C.
Sent: Friday, March 22, 2019 2:12 PM
To: 'Bauer.jeff@Epa.gov' <Bauer.jeff@Epa.gov>; 'Schweer, Greg' <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: **Ex. 4 CBI**

Hi folks –

I hope you are doing well. Jeff – this is the PMN case that my colleague, Dr. Rhys Daniels, spoke with you about earlier this week.

The issue is development of data needed to amend the existing section 5(e) order for this substance to add an additional use, and EPA approval of protocols for same. Would the Agency be available for a short conference call on this on one of the following days?:

- March 27 (except 12-2 ET)
- April 2
- April 3
- April 4

This is becoming more urgent from a commercial standpoint.

Thanks much - Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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Message

From: Berger, Tom C. [Berger@khlaw.com]
Sent: 6/15/2020 8:04:35 PM
To: Bauer, Jeff [Bauer.Jeff@epa.gov]
CC: Price, Amanda [price@khlaw.com]; Schweer, Greg [Schweer.Greg@epa.gov]; Daniels, Rhys G. [daniels@khlaw.com]; Edelstein, Rebecca [Edelstein.Rebecca@epa.gov]; Alwood, Jim [Alwood.Jim@epa.gov]; Moss, Kenneth [Moss.Kenneth@epa.gov]
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope you had a great weekend.

We had our call on May 27 and the submitter is inquiring as to status. The questions/topics at issue are:

- (1) Scheduling a call on the 5(e)/SNUR case at issue; and
- (2) The issue of whether when a section 5(e) order is modified or revoked, does EPA “automatically” seek to amend or revoke the corresponding SNUR accordingly?

Thanks again - Tom

From: Berger, Tom C.
Sent: Tuesday, June 9, 2020 12:53 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; alwood.jim@epa.gov; Moss, Kenneth <Moss.Kenneth@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>
Subject: RE: **Ex. 4 CBI**

Hi folks –

Sorry to be a pest but just checking in again.

Thanks again - Tom

From: Berger, Tom C.
Sent: Thursday, June 4, 2020 10:12 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; alwood.jim@epa.gov; Moss, Kenneth <Moss.Kenneth@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>
Subject: RE: **Ex. 4 CBI**

Hi folks –

Just checking in on the below two items.

Thanks again - Tom

From: Berger, Tom C.
Sent: Monday, June 1, 2020 5:55 PM

To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>; 'alwood.jim@epa.gov' <alwood.jim@epa.gov>; 'Moss, Kenneth' <Moss.Kenneth@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; 'Schweer, Greg' <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; 'Edelstein, Rebecca' <Edelstein.Rebecca@epa.gov>

Subject: RE: **Ex. 4 CBI**

Hi folks –

I hope you had a great weekend!

Just checking in on:

- (1) Scheduling a call on the 5(e)/SNUR case at issue; and
- (2) The issue of whether when a section 5(e) order is modified or revoked, does EPA “automatically” seek to amend or revoke the corresponding SNUR accordingly?

Thanks all - Tom

From: Berger, Tom C.

Sent: Thursday, May 28, 2020 12:23 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; alwood.jim@epa.gov; Moss, Kenneth <Moss.Kenneth@epa.gov>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just following up on this.

Also (and I am cc:ing Jim Alwood and Ken Moss), per our discussions, if and when the section 5(e) order at issue here is modified (or perhaps even revoked), would EPA “automatically” seek to amend or revoke the corresponding SNUR accordingly? As we discussed, as there are dozens of processors interested in the “new use” being sought, filing one or more SNUNs is not workable. However, the PMN submitter/manufacturer could submit a request to amend or revoke the SNUR under 721.185(b)(1).

Thanks again – Tom

From: Berger, Tom C.

Sent: Wednesday, May 27, 2020 2:57 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Thanks for taking the time to meet with us. Should we pencil in a time two weeks from now (i.e., June 9 or June 11) for our next call?

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, May 13, 2020 1:32 PM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom,

I sent a meeting request to you three for May 27th at 2 p.m. to give a status update as requested.

Thanks

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

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Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Wednesday, May 13, 2020 12:53 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just seeing if it makes sense to set up a conference call in a week or two.

Thanks much again - Tom

From: Berger, Tom C.
Sent: Friday, May 8, 2020 11:14 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Jeff/Greg – thanks again.

Can/should we schedule a conference call with the submitter in a week or two?

Happy Friday!

Tom

From: Berger, Tom C.
Sent: Thursday, May 7, 2020 4:17 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: Re: **Ex. 4 CBI**

Jeff - thanks much.

Tom

On May 7, 2020, at 4:03 PM, Bauer, Jeff <Bauer.Jeff@epa.gov> wrote:

Tom, I hope you hanging in there as well, I have an email out to see if I can get a status update on the Assessor and to address you questions sent into CDX for a meeting.

Jeff

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
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<http://www.epa.gov/oppt/newchemicals/>

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Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Thursday, May 07, 2020 1:57 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff – Just touching base as the submitter has requested a status update.

Thanks again - Tom

From: Berger, Tom C.
Sent: Tuesday, May 5, 2020 11:56 AM
To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; 'Schweer, Greg' <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff – Just checking in on this – thanks - Tom

From: Berger, Tom C.
Sent: Wednesday, April 29, 2020 11:12 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I just thought I would check in on this and see if the Agency needs any additional information.

Thanks again and best regards,
Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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From: Berger, Tom C.
Sent: Thursday, April 23, 2020 7:13 PM
To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Jeff - thanks much.

Your recent voicemail and follow-up email indicated that the EPA Chemist has evaluated the study” on **Ex. 4 CBI** but that the reviewer did have a few questions and comments: **Ex. 4 CBI**

Ex. 4 CBI

Ex. 4 CBI

To specifically answer the Chemist's questions:

Ex. 4 CBI

Ex. 4 CBI

* * *

We trust that you find this information useful in resolved all outstanding issues. As always, if you have any questions please do not hesitate to contact us.

Best regards,
Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Tuesday, April 21, 2020 5:17 PM
To: Daniels, Rhys G. <daniels@khlaw.com>; Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: **Ex. 4 CBI**

I am moving forward with the review based on the information I have on the two studies, I wanted to share with you her comments on the test. **Ex. 4 CBI**

Ex. 4 CBI RAD has the information and I am trying to get them to do the risk assessment based on **Ex. 4 CBI**

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

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1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Daniels, Rhys G. <daniels@khlaw.com>
Sent: Tuesday, April 21, 2020 4:58 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: **Ex. 4 CBI**

Jeff,

As always, we hope that all is well.

Per your recent voicemail and follow-up email concerning the **Ex. 4 CBI** case, we understand that the chemist has two questions concerning the **Ex. 4 CBI**

Ex. 4 CBI

Thanks in advance for your response.

Rhys G. Daniels, Ph.D.
Staff Scientist
tel: +1 202.434.4270 | fax: +1 202.434.4646 | daniels@khlaw.com

1001 G Street NW, Suite 500 West | Washington, DC 20001

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Thursday, April 16, 2020 1:02 PM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: Ex. 4 CBI

Tom,

The chemist sent me a memo Ex. 4 CBI and they had two questions, I called and left you a message today Ex. 4 CBI I sent RAD a request last week to update the HH assessment Ex. 4 CBI as in my April 4, 2020 email to you. I have two emails into RAD on this case and will try an update you again in a week or so. I requested RAD set up a date with me to have a meeting to discuss how to proceed with this PMN.

Thanks
Jeff

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

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1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Thursday, April 16, 2020 12:28 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: Ex. 4 CBI

Hi Jeff –

I hope that all is well.

Just checking in re status update. A non-CBI-containing email from you would probably be the best (if needed at some later time we can use EPA's new CBI via email authorization form if the submitter agrees).

Thanks again – Tom

From: Berger, Tom C.
Sent: Wednesday, April 8, 2020 11:06 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Jeff – thanks much for the update. Hope you and all at EPA are staying safe.

Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, April 8, 2020 11:03 AM
To: Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom,

Ex. 4 CBI

I will follow up with you next wed with a status update.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

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1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Wednesday, April 08, 2020 10:48 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>
Subject: **Ex. 4 CBI**

Hi Greg –

I was just going through my to-do list and thought I would circle back on these two cases. I hope everyone is hanging in there.

Thanks again – Tom

From: Berger, Tom C.

Sent: Monday, March 30, 2020 3:46 PM

To: Schweer, Greg <Schweer.Greg@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Greg / all – completely understood – thank you so much.

Tom

From: Schweer, Greg <Schweer.Greg@epa.gov>

Sent: Monday, March 30, 2020 3:42 PM

To: Berger, Tom C. <Berger@khlaw.com>

Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>

Subject: RE: **Ex. 4 CBI**

Hi Tom.

I am not ignoring you. I did check with Jeff Bauer early last week on this case. He filled me in on the requests he had made of RAD to review submitted test data and your request for a meeting. However, believe it or not, we have been having issues reliably being able to access our CBI-secure LAN. This hampers our ability to efficiently complete work. I will check on the status of your case as soon as I can.

From: Berger, Tom C. <Berger@khlaw.com>

Sent: Monday, March 30, 2020 11:51 AM

To: Schweer, Greg <Schweer.Greg@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Greg –

Hope all is well.

Just thought I would check in with you on the **Ex. 4 CBI** LVEA (Lauren Davis) and **Ex. 4 CBI** **Ex. 4 CBI** with Jeff Bauer.

Thanks all always - Tom

From: Berger, Tom C.

Sent: Tuesday, March 24, 2020 11:12 AM

To: Schweer, Greg <Schweer.Greg@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Greg – thanks so much as always. I also have an LVE with Lauren Davis:

Ex. 4 CBI

Ex. 4 CBI held up in the process. Lauren has been responsive but the case has stalled (again, however, I understand the challenges you are facing).

These are my two “priority” cases.

Tom

From: Schweer, Greg <Schweer.Greg@epa.gov>

Sent: Tuesday, March 24, 2020 11:07 AM

To: Berger, Tom C. <Berger@khlaw.com>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: Re: **Ex. 4 CBI**

Tom,

Yes, things are a bit crazy. I will check into the case status today or tomorrow.

Sent from my iPhone

On Mar 24, 2020, at 10:48 AM, Berger, Tom C. <Berger@khlaw.com> wrote:

Hi Greg –

Obviously things are crazy and I don’t want to push Jeff too hard but no response from Jeff on this case for a month.

Hang in there....

Tom

From: Berger, Tom C.

Sent: Monday, March 23, 2020 6:22 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies – just want to make sure you are getting these emails. Understand if there are delays.

Tom

From: Berger, Tom C.

Sent: Thursday, March 19, 2020 5:22 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff – checking in again – thanks - Tom

From: Berger, Tom C.
Sent: Monday, March 16, 2020 1:40 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I know things are crazy but checking in again – thanks - Tom

From: Berger, Tom C.
Sent: Wednesday, March 11, 2020 3:43 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Checking in again - thanks

From: Berger, Tom C.
Sent: Friday, March 6, 2020 1:33 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

The submitter is quite anxious – can we touch base next week?

Thanks much - Tom

From: Berger, Tom C.
Sent: Tuesday, February 25, 2020 9:08 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just checking in on this – thanks - Tom

From: Berger, Tom C.
Sent: Thursday, February 20, 2020 12:18 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope that all is well.

Per our discussions, the submitter has modified the questions to focus on toxicity/risk issues and submitted them via CDX yesterday. Can we start looking at conference call dates the week of March 9?

Thanks and best regards,
Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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From: Berger, Tom C.
Sent: Wednesday, January 29, 2020 11:41 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies we keep playing phone tag – can we discuss how to convert the below questions into questions that would be acceptable to RAD so we can schedule a call with you and RAD? Your voicemail suggested the below are more legal/regulatory than risk-based questions. We still need the below questions answered – perhaps we tee up the more scientific ones for RAD then have the call to address both types of questions. The submitter is under growing commercial pressure.

Thanks much again - Tom

From: Berger, Tom C.
Sent: Monday, January 20, 2020 3:50 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies that we could not connect last week. Let's try to touch base tomorrow (Tuesday) if possible to discuss how to move this forward.

Thanks again – Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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From: Berger, Tom C.
Sent: Monday, January 13, 2020 2:50 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**
Importance: High

Hi Jeff –

Following is the list of questions we are considering submitting through CDX. Please let me know if these look ok.

Thanks again and best regards,
Tom

* * *

*(1) Based on review of the submitted physical-chemical properties test data, does EPA now agree that use **Ex. 4 CBI** as described in the PMN poses no unreasonable risk of injury and so plans to revoke the consent order?*

(2) If so, what is the process for revoking the current consent order? Does the submitter now need to request that EPA revoke the order, or will EPA itself initiate revocation? What is the expected timing for revocation? How would EPA communicate such revocation?

(3) How would revocation of the consent order impact the final SNUR for the subject substance?

(4) Would a SNUN be a more expedient approach?

* * *

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, January 8, 2020 8:56 AM
To: Berger, Tom C. <Berger@khlaw.com>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Tom, I am expecting information from the engineer today or tomorrow on the spay test, I left you a message. There is a new procedure for us to set up meeting with RAD. I am to have the submitter send in a list of questions for RAD, they will assign someone up there as a Lead person who has two weeks and will set a date for when we can have a meeting. This may be our best route to other than just me bugging them to get things done. There were a series of emails on this case last week but now everyone is back from the holidays I am trying to get this case moving again.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>

Sent: Tuesday, January 07, 2020 4:16 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope you had a great holiday! The client was wondering if we could have a conference call on this, this week or next. Please advise.

Thanks much – Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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From: Berger, Tom C.
Sent: Tuesday, December 10, 2019 2:10 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just checking back in – thanks - Tom

From: Berger, Tom C.
Sent: Thursday, December 5, 2019 9:46 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

When we spoke before Thanksgiving (I hope you had a great one!) you indicated that the reports were being reviewed and that I should reach out to you in early December.

Is there any update?

Thanks much and best regards – Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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From: Berger, Tom C.
Sent: Monday, November 18, 2019 1:17 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

The PMN submitter asked me to reach out to you to see if we can schedule a conference call (including EPA, K&H, and the submitter) on this case re status and pathforward.

Thanks - Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Friday, March 29, 2019 5:43 PM
To: Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom,
I set the meeting up for Wednesday April 3, at 11 am. RAD has accepted the invitation for that time.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Bauer, Jeff
Sent: Tuesday, March 26, 2019 11:37 AM
To: 'Berger, Tom C.' <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom, I left you a voice message, I am seeing what time it best for RAD to be part of the call.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Tuesday, March 26, 2019 11:30 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi folks –

Just thought I would check in with you on this.

Thanks again - Tom

From: Berger, Tom C.
Sent: Friday, March 22, 2019 2:12 PM
To: 'Bauer.jeff@Epa.gov' <Bauer.jeff@Epa.gov>; 'Schweer, Greg' <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: **Ex. 4 CBI**

Hi folks –

I hope you are doing well. Jeff – this is the PMN case that my colleague, Dr. Rhys Daniels, spoke with you about earlier this week.

The issue is development of data needed to amend the existing section 5(e) order for this substance to add an additional use, and EPA approval of protocols for same. Would the Agency be available for a short conference call on this on one of the following days?:

- March 27 (except 12-2 ET)
- April 2
- April 3
- April 4

This is becoming more urgent from a commercial standpoint.

Thanks much - Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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Message

From: LaFore, Mike (M) [m.lafore@dow.com]
Sent: 6/12/2020 12:05:43 PM
To: Hilton, Geraldine [Hilton.Geraldine@epa.gov]; Edelstein, Rebecca [Edelstein.Rebecca@epa.gov]
CC: Schweer, Greg [Schweer.Greg@epa.gov]; Sullivan, Andrew [sullivan.andrew@epa.gov]; Yan, James [Yan.James@epa.gov]; LaFore, Mike (M) [m.lafore@dow.com]
Subject: RE: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19
Attachments: Dow - Authorization Form for CBI transmittal by e-mail.pdf

Hello Geraldine and Rebecca,

Please find attached the completed Authorization Form for CBI transmittal by e-mail.

Thank you!

Best regards,

Mike LaFore

North America Product Regulatory Services Leader
Lead TSCA EHS Regulatory Manager

Dow

633 Washington Street, Midland, MI 48667
phone: 989.496.8393 | email: m.lafore@dow.com
fax: 989.636.1875



From: Hilton, Geraldine <Hilton.Geraldine@epa.gov>
Sent: Wednesday, June 10, 2020 2:50 PM
To: LaFore, Mike (M) <m.lafore@dow.com>
Cc: Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>; Sullivan, Andrew <sullivan.andrew@epa.gov>; Yan, James <Yan.James@epa.gov>
Subject: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19

Dear Mr. LaFore:

In an effort to encourage social distancing and help reduce community spread of COVID-19, most EPA staff have been authorized to telework. With a majority of EPA staff now teleworking from remote sites, some minor changes to the normal TSCA section 5 review processes, including the TSCA section 5(a)(3) determination processes, are required. Specifically, the normal process by which section 5(a)(3)(C) determination documents, section 5(e) orders, and assessment reports are transmitted to submitters, because they contain information claimed as CBI, are hard copies submitted by the mail or courier services and via fax machines. These methods of delivery are not available from remote sites and therefore other means of transmitting this information must be utilized.

Given this extraordinary situation, and to avoid delay in addressing TSCA section 5 requirements, the Agency is offering an option to allowed affected persons to agree to allow EPA to transmit these materials via normal non-encrypted Outlook email. If you agree to this, the Agency will transmit these documents to you via email during the period in which a majority of EPA staff is teleworking. In the absence of this agreement EPA may need to extend the review period for your submission or issue a unilateral order under Section 5(e). Please note that EPA is not requiring companies to agree to transmission via email. Rather this communication explains the constraints we are acting under, and the delays that would result in the absence of email transmission. Companies are free to choose as appropriate.

Also, please note that agreeing to this process is a limited waiver of the TSCA CBI procedural protections, which generally restricts the transmission of CBI over a non-encrypted email system. That said, EPA's email system is compliant with all applicable Federal government information security provisions, including the Federal Information Security Management Act, and EPA's email systems meet the level of protection required for storing and transmitting CBI. Furthermore, your agreement will not constitute a waiver of substantive CBI protections, meaning that the information transmitted and claimed as confidential will only be disclosed consistent with TSCA, other applicable laws, and associated implementing regulations.

If you wish to grant EPA a limited waiver to transmit the materials via EPA's email system during the period in which a majority of EPA staff is teleworking, please have your authorized representative complete (e.g., **add the case number to the body and heading**), sign, and return the attached to Rebecca Edelstein (Edelstein.Rebecca@epa.gov) as well as to any EPA staff who were cc'd on the email sent to you. If you have any questions about this communication or the described process, please contact Rebecca Edelstein at (202) 564-1667 or the EPA Program Manager assigned to the case.


Geraldine Hilton
Program Manager
New Chemical Management Branch (7405M)
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460
(202) 564-8986, (202)564-9490 (fax)

For Courier Deliveries:
1201 Constitution Avenue, NW Rm. 4133E
Washington, D.C. 20004

Agreement to authorize transmittal of TSCA Confidential Business Information (CBI) via Outlook email by designated Agency representatives during the period of EPA telework due to COVID-19

Documents concerning: PMN-16-0180

Dow authorizes EPA to transmit documents related to the above referenced TSCA submission, including information claimed as CBI, to **Dow** (or its technical contact listed on the PMN form) through EPA's Outlook email system. This authorization applies only during those periods where EPA staff working on PMN-16-0180 are teleworking due to COVID-19 concerns and may be withdrawn at any time. Nothing in this authorization diminishes or otherwise limits **Dow's** protections under TSCA to assert information as CBI, or otherwise authorizes the release of any information claimed as CBI without exhausting all provisions of TSCA protecting the release of such information. I have the authority to sign this on behalf of **Dow**.

Signature of authorized person:  _____
Name of authorized person printed or typed: Mike LaFore _____
Title: North America Product Regulatory Services Leader _____
Email address: m.lafore@dow.com _____
Telephone number: Ex. 6 Personal Privacy (PP) _____
COMPANY Dow _____

Message

From: Hilton, Geraldine [Hilton.Geraldine@epa.gov]
Sent: 6/10/2020 6:50:29 PM
To: LaFore, Mike (M) [m.lafore@dow.com]
CC: Edelstein, Rebecca [Edelstein.Rebecca@epa.gov]; Schweer, Greg [Schweer.Greg@epa.gov]; Sullivan, Andrew [sullivan.andrew@epa.gov]; Yan, James [Yan.James@epa.gov]
Subject: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19
Attachments: Authorization Form for CBI transmittal by e-mail (003).docx

Dear Mr. LaFore:

In an effort to encourage social distancing and help reduce community spread of COVID-19, most EPA staff have been authorized to telework. With a majority of EPA staff now teleworking from remote sites, some minor changes to the normal TSCA section 5 review processes, including the TSCA section 5(a)(3) determination processes, are required. Specifically, the normal process by which section 5(a)(3)(C) determination documents, section 5(e) orders, and assessment reports are transmitted to submitters, because they contain information claimed as CBI, are hard copies submitted by the mail or courier services and via fax machines. These methods of delivery are not available from remote sites and therefore other means of transmitting this information must be utilized.

Given this extraordinary situation, and to avoid delay in addressing TSCA section 5 requirements, the Agency is offering an option to allowed affected persons to agree to allow EPA to transmit these materials via normal non-encrypted Outlook email. If you agree to this, the Agency will transmit these documents to you via email during the period in which a majority of EPA staff is teleworking. In the absence of this agreement EPA may need to extend the review period for your submission or issue a unilateral order under Section 5(e). Please note that EPA is not requiring companies to agree to transmission via email. Rather this communication explains the constraints we are acting under, and the delays that would result in the absence of email transmission. Companies are free to choose as appropriate.

Also, please note that agreeing to this process is a limited waiver of the TSCA CBI procedural protections, which generally restricts the transmission of CBI over a non-encrypted email system. That said, EPA's email system is compliant with all applicable Federal government information security provisions, including the Federal Information Security Management Act, and EPA's email systems meet the level of protection required for storing and transmitting CBI. Furthermore, your agreement will not constitute a waiver of substantive CBI protections, meaning that the information transmitted and claimed as confidential will only be disclosed consistent with TSCA, other applicable laws, and associated implementing regulations.

If you wish to grant EPA a limited waiver to transmit the materials via EPA's email system during the period in which a majority of EPA staff is teleworking, please have your authorized representative complete (e.g., **add the case number to the body and heading**), sign, and return the attached to Rebecca Edelstein (Edelstein.Rebecca@epa.gov) as well as to any EPA staff who were cc'd on the email sent to you. If you have any questions about this communication or the described process, please contact Rebecca Edelstein at (202) 564-1667 or the EPA Program Manager assigned to the case.

Geraldine Hilton
Program Manager
New Chemical Management Branch (7405M)

U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460
(202) 564-8986, (202)564-9490 (fax)

For Courier Deliveries:

1201 Constitution Avenue, NW Rm. 4133E
Washington, D.C. 20004

Agreement to authorize transmittal of TSCA Confidential Business Information (CBI) via Outlook email by designated Agency representatives during the period of EPA telework due to COVID-19

Documents concerning: PMN-XX-XXX

COMPANY authorizes EPA to transmit documents related to the above referenced TSCA submission, including information claimed as CBI, to **COMPANY** (or its technical contact listed on the PMN form) through EPA's Outlook email system. This authorization applies only during those periods where EPA staff working on PMN-XX-XXX are teleworking due to COVID-19 concerns and may be withdrawn at any time. Nothing in this authorization diminishes or otherwise limits **COMPANY'S** protections under TSCA to assert information as CBI, or otherwise authorizes the release of any information claimed as CBI without exhausting all provisions of TSCA protecting the release of such information. I have the authority to sign this on behalf of **COMPANY**

Signature of authorized person: _____

Name of authorized person printed or typed: _____

Title: _____

Email address: _____

Telephone number: _____

COMPANY _____

Message

From: Berger, Tom C. [Berger@khlaw.com]
Sent: 6/9/2020 4:53:04 PM
To: Bauer, Jeff [Bauer.Jeff@epa.gov]; Alwood, Jim [Alwood.Jim@epa.gov]; Moss, Kenneth [Moss.Kenneth@epa.gov]
CC: Price, Amanda [price@khlaw.com]; Schweer, Greg [Schweer.Greg@epa.gov]; Daniels, Rhys G. [daniels@khlaw.com]; Edelstein, Rebecca [Edelstein.Rebecca@epa.gov]
Subject: RE: **Ex. 4 CBI**

Hi folks –

Sorry to be a pest but just checking in again.

Thanks again - Tom

From: Berger, Tom C.
Sent: Thursday, June 4, 2020 10:12 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; alwood.jim@epa.gov; Moss, Kenneth <Moss.Kenneth@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>
Subject: RE: **Ex. 4 CBI**

Hi folks –

Just checking in on the below two items.

Thanks again - Tom

From: Berger, Tom C.
Sent: Monday, June 1, 2020 5:55 PM
To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>; 'alwood.jim@epa.gov' <alwood.jim@epa.gov>; 'Moss, Kenneth' <Moss.Kenneth@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; 'Schweer, Greg' <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; 'Edelstein, Rebecca' <Edelstein.Rebecca@epa.gov>
Subject: RE: **Ex. 4 CBI**

Hi folks –

I hope you had a great weekend!

Just checking in on:

- (1) Scheduling a call on the 5(e)/SNUR case at issue; and
- (2) The issue of whether when a section 5(e) order is modified or revoked, does EPA “automatically” seek to amend or revoke the corresponding SNUR accordingly?

Thanks all - Tom

From: Berger, Tom C.
Sent: Thursday, May 28, 2020 12:23 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; alwood.jim@epa.gov; Moss, Kenneth <Moss.Kenneth@epa.gov>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just following up on this.

Also (and I am cc'ing Jim Alwood and Ken Moss), per our discussions, if and when the section 5(e) order at issue here is modified (or perhaps even revoked), would EPA “automatically” seek to amend or revoke the corresponding SNUR accordingly? As we discussed, as there are dozens of processors interested in the “new use” being sought, filing one or more SNUNs is not workable. However, the PMN submitter/manufacture could submit a request to amend or revoke the SNUR under 721.185(b)(1).

Thanks again – Tom

From: Berger, Tom C.

Sent: Wednesday, May 27, 2020 2:57 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Thanks for taking the time to meet with us. Should we pencil in a time two weeks from now (i.e., June 9 or June 11) for our next call?

From: Bauer, Jeff <Bauer.Jeff@epa.gov>

Sent: Wednesday, May 13, 2020 1:32 PM

To: Berger, Tom C. <Berger@khlaw.com>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Tom,

I sent a meeting request to you three for May 27th at 2 p.m. to give a status update as requested.

Thanks

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Wednesday, May 13, 2020 12:53 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just seeing if it makes sense to set up a conference call in a week or two.

Thanks much again - Tom

From: Berger, Tom C.
Sent: Friday, May 8, 2020 11:14 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Jeff/Greg – thanks again.

Can/should we schedule a conference call with the submitter in a week or two?

Happy Friday!

Tom

From: Berger, Tom C.
Sent: Thursday, May 7, 2020 4:17 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: Re: **Ex. 4 CBI**

Jeff - thanks much.

Tom

On May 7, 2020, at 4:03 PM, Bauer, Jeff <Bauer.Jeff@epa.gov> wrote:

Tom, I hope you hanging in there as well, I have an email out to see if I can get a status update on the Assessor and to address you questions sent into CDX for a meeting.

Jeff

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)

Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Thursday, May 07, 2020 1:57 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: Ex. 4 CBI

Hi Jeff – Just touching base as the submitter has requested a status update.

Thanks again - Tom

From: Berger, Tom C.
Sent: Tuesday, May 5, 2020 11:56 AM
To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; 'Schweer, Greg' <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: Ex. 4 CBI

Hi Jeff – Just checking in on this – thanks - Tom

From: Berger, Tom C.
Sent: Wednesday, April 29, 2020 11:12 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: Ex. 4 CBI

Hi Jeff –

I just thought I would check in on this and see if the Agency needs any additional information.

Thanks again and best regards,
Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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From: Berger, Tom C.

Sent: Thursday, April 23, 2020 7:13 PM

To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Jeff - thanks much.

Your recent voicemail and follow-up email indicated that the EPA Chemist has evaluated the study" on **Ex. 4 CBI** but that the reviewer did have a few questions and comments:

Ex. 4 CBI

Ex. 4 CBI

Ex. 4 CBI

To specifically answer the Chemist's questions:

Ex. 4 CBI

Ex. 4 CBI

* * *

We trust that you find this information useful in resolved all outstanding issues. As always, if you have any questions please do not hesitate to contact us.

Best regards,
Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Tuesday, April 21, 2020 5:17 PM
To: Daniels, Rhys G. <daniels@khlaw.com>; Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: **Ex. 4 CBI**

I am moving forward with the review based on the information I have on the two studies, I wanted to share with you her comments on the test. **Ex. 4 CBI**

Ex. 4 CBI	RAD has the
information and I am trying to get them to do the risk assessment based on	Ex. 4 CBI

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Daniels, Rhys G. <daniels@khlaw.com>
Sent: Tuesday, April 21, 2020 4:58 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: **Ex. 4 CBI**

Jeff,

As always, we hope that all is well.

Per your recent voicemail and follow-up email concerning the **Ex. 4 CBI** case, we understand that the chemist has two questions concerning **Ex. 4 CBI**

Ex. 4 CBI

Thanks in advance for your response.

Rhys G. Daniels, Ph.D.
Staff Scientist
tel: +1 202.434.4270 | fax: +1 202.434.4646 | daniels@khlaw.com
1001 G Street NW, Suite 500 West | Washington, DC 20001

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Thursday, April 16, 2020 1:02 PM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: **Ex. 4 CBI**

Tom,

The chemist sent me a memo **Ex. 4 CBI** and they had two questions, I called and left you a message today **Ex. 4 CBI** I sent RAD a request last week to update the HH assessment **Ex. 4 CBI** as in my April 4, 2020 email to you. I have two emails into RAD on this case and will try an update you again in a week or

so. I requested RAD set up a date with me to have a meeting to discuss how to proceed with this PMN.

Thanks
Jeff

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

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1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Thursday, April 16, 2020 12:28 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: Ex. 4 CBI

Hi Jeff –

I hope that all is well.

Just checking in re status update. A non-CBI-containing email from you would probably be the best (if needed at some later time we can use EPA's new CBI via email authorization form if the submitter agrees).

Thanks again – Tom

From: Berger, Tom C.
Sent: Wednesday, April 8, 2020 11:06 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>
Subject: RE: Ex. 4 CBI

Jeff – thanks much for the update. Hope you and all at EPA are staying safe.

Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, April 8, 2020 11:03 AM
To: Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>
Subject: RE: Ex. 4 CBI

Tom,

Ex. 4 CBI

I will follow up with you next wed with a status update.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

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Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Wednesday, April 08, 2020 10:48 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Greg –

I was just going through my to-do list and thought I would circle back on these two cases. I hope everyone is hanging in there.

Thanks again – Tom

From: Berger, Tom C.
Sent: Monday, March 30, 2020 3:46 PM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Greg / all – completely understood – thank you so much.

Tom

From: Schweer, Greg <Schweer.Greg@epa.gov>
Sent: Monday, March 30, 2020 3:42 PM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>
Subject: RE: **Ex. 4 CBI**

Hi Tom.

I am not ignoring you. I did check with Jeff Bauer early last week on this case. He filled me in on the requests he had made of RAD to review submitted test data and your request for a meeting. However, believe it or not, we have been having issues reliably being able to access our CBI-secure LAN. This hampers our ability to efficiently complete work. I will check on the status of your case as soon as I can.

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Monday, March 30, 2020 11:51 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: Ex. 4 CBI

Hi Greg –

Hope all is well.

Just thought I would check in with you on the Ex. 4 CBI LVEA (Lauren Davis) and Ex. 4 CBI Ex. 4 CBI) with Jeff Bauer.

Thanks all always - Tom

From: Berger, Tom C.
Sent: Tuesday, March 24, 2020 11:12 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: Ex. 4 CBI

Greg – thanks so much as always. I also have an LVE with Lauren Davis Ex. 4 CBI Ex. 4 CBI held up in the process. Lauren has been responsive but the case has stalled (again, however, I understand the challenges you are facing).

These are my two “priority” cases.

Tom

From: Schweer, Greg <Schweer.Greg@epa.gov>
Sent: Tuesday, March 24, 2020 11:07 AM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: Re: Ex. 4 CBI

Tom,

Yes, things are a bit crazy. I will check into the case status today or tomorrow.

Sent from my iPhone

On Mar 24, 2020, at 10:48 AM, Berger, Tom C. <Berger@khlaw.com> wrote:

Hi Greg –

Obviously things are crazy and I don't want to push Jeff too hard but no response from Jeff on this case for a month.

Hang in there....

Tom

From: Berger, Tom C.
Sent: Monday, March 23, 2020 6:22 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies – just want to make sure you are getting these emails. Understand if there are delays.

Tom

From: Berger, Tom C.
Sent: Thursday, March 19, 2020 5:22 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff – checking in again – thanks - Tom

From: Berger, Tom C.
Sent: Monday, March 16, 2020 1:40 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I know things are crazy but checking in again – thanks - Tom

From: Berger, Tom C.
Sent: Wednesday, March 11, 2020 3:43 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Checking in again - thanks

From: Berger, Tom C.
Sent: Friday, March 6, 2020 1:33 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

The submitter is quite anxious – can we touch base next week?

Thanks much - Tom

From: Berger, Tom C.
Sent: Tuesday, February 25, 2020 9:08 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just checking in on this – thanks - Tom

From: Berger, Tom C.
Sent: Thursday, February 20, 2020 12:18 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope that all is well.

Per our discussions, the submitter has modified the questions to focus on toxicity/risk issues and submitted them via CDX yesterday. Can we start looking at conference call dates the week of March 9?

Thanks and best regards,
Tom

Thomas C. Berger
Partner
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From: Berger, Tom C.
Sent: Wednesday, January 29, 2020 11:41 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies we keep playing phone tag – can we discuss how to convert the below questions into questions that would be acceptable to RAD so we can schedule a call with you and RAD? Your voicemail suggested the below are more legal/regulatory than risk-based questions. We still need the below questions answered – perhaps we tee up the more scientific ones for RAD then have the call to address both types of questions. The submitter is under growing commercial pressure.

Thanks much again - Tom

From: Berger, Tom C.
Sent: Monday, January 20, 2020 3:50 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies that we could not connect last week. Let's try to touch base tomorrow (Tuesday) if possible to discuss how to move this forward.

Thanks again – Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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From: Berger, Tom C.
Sent: Monday, January 13, 2020 2:50 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**
Importance: High

Hi Jeff –

Following is the list of questions we are considering submitting through CDX. Please let me know if these look ok.

Thanks again and best regards,
Tom

* * *

*(1) Based on review of the submitted physical-chemical properties test data, does EPA now agree that use **Ex. 4 CBI** as described in the PMN poses no unreasonable risk of injury and so plans to revoke the consent order?*

(2) If so, what is the process for revoking the current consent order? Does the submitter now need to request that EPA revoke the order, or will EPA itself initiate revocation? What is the expected timing for revocation? How would EPA communicate such revocation?

(3) How would revocation of the consent order impact the final SNUR for the subject substance?

(4) Would a SNUN be a more expedient approach?

* * *

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, January 8, 2020 8:56 AM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom, I am expecting information from the engineer today or tomorrow on the **Ex. 4 CBI** test. I left you a message. There is a new procedure for us to set up meeting with RAD. I am to have the submitter send in a list of questions for RAD, they will assign someone up there as a Lead person who has two weeks and will set a date for when we can have a meeting. This may be our best route to other than just me bugging them to get things done. There were a series of emails on this case last week but now everyone is back from the holidays I am trying to get this case moving again.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

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Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Tuesday, January 07, 2020 4:16 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope you had a great holiday! The client was wondering if we could have a conference call on this, this week or next. Please advise.

Thanks much – Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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From: Berger, Tom C.
Sent: Tuesday, December 10, 2019 2:10 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just checking back in – thanks - Tom

From: Berger, Tom C.
Sent: Thursday, December 5, 2019 9:46 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

When we spoke before Thanksgiving (I hope you had a great one!) you indicated that the reports were being reviewed and that I should reach out to you in early December.

Is there any update?

Thanks much and best regards – Tom

Thomas C. Berger

Partner

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From: Berger, Tom C.

Sent: Monday, November 18, 2019 1:17 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

The PMN submitter asked me to reach out to you to see if we can schedule a conference call (including EPA, K&H, and the submitter) on this case re status and pathforward.

Thanks - Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>

Sent: Friday, March 29, 2019 5:43 PM

To: Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Tom,

I set the meeting up for Wednesday April 3, at 11 am. RAD has accepted the invitation for that time.

Jeff Bauer - Program Manager

United States Environmental Protection Agency (USEPA)

Office of Pollution Prevention and Toxics (OPPT)

New Chemicals Program (7405M)

<http://www.epa.gov/oppt/newchems/>

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1201 Constitution Ave., NW

Washington, DC 20004

Phone: 202-564-9042, Fax: 202-564-9490

From: Bauer, Jeff

Sent: Tuesday, March 26, 2019 11:37 AM

To: 'Berger, Tom C.' <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Tom, I left you a voice message, I am seeing what time it best for RAD to be part of the call.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>

Sent: Tuesday, March 26, 2019 11:30 AM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi folks –

Just thought I would check in with you on this.

Thanks again - Tom

From: Berger, Tom C.

Sent: Friday, March 22, 2019 2:12 PM

To: 'Bauer.jeff@Epa.gov' <Bauer.jeff@Epa.gov>; 'Schweer, Greg' <Schweer.Greg@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: **Ex. 4 CBI**

Hi folks –

I hope you are doing well. Jeff – this is the PMN case that my colleague, Dr. Rhys Daniels, spoke with you about earlier this week.

The issue is development of data needed to amend the existing section 5(e) order for this substance to add an additional use, and EPA approval of protocols for same. Would the Agency be available for a short conference call on this on one of the following days?:

- March 27 (except 12-2 ET)
- April 2
- April 3
- April 4

This is becoming more urgent from a commercial standpoint.

Thanks much - Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com

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Message

From: Berger, Tom C. [Berger@khlaw.com]
Sent: 6/4/2020 2:11:32 PM
To: Bauer, Jeff [Bauer.Jeff@epa.gov]; Alwood, Jim [Alwood.Jim@epa.gov]; Moss, Kenneth [Moss.Kenneth@epa.gov]
CC: Price, Amanda [price@khlaw.com]; Schweer, Greg [Schweer.Greg@epa.gov]; Daniels, Rhys G. [daniels@khlaw.com]; Edelstein, Rebecca [Edelstein.Rebecca@epa.gov]
Subject: RE: P **Ex. 4 CBI**

Hi folks –

Just checking in on the below two items.

Thanks again - Tom

From: Berger, Tom C.
Sent: Monday, June 1, 2020 5:55 PM
To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>; 'alwood.jim@epa.gov' <alwood.jim@epa.gov>; 'Moss, Kenneth' <Moss.Kenneth@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; 'Schweer, Greg' <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; 'Edelstein, Rebecca' <Edelstein.Rebecca@epa.gov>
Subject: RE: **Ex. 4 CBI**

Hi folks –

I hope you had a great weekend!

Just checking in on:

- (1) Scheduling a call on the 5(e)/SNUR case at issue; and
- (2) The issue of whether when a section 5(e) order is modified or revoked, does EPA “automatically” seek to amend or revoke the corresponding SNUR accordingly?

Thanks all - Tom

From: Berger, Tom C.
Sent: Thursday, May 28, 2020 12:23 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; alwood.jim@epa.gov; Moss, Kenneth <Moss.Kenneth@epa.gov>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just following up on this.

Also (and I am cc:ing Jim Alwood and Ken Moss), per our discussions, if and when the section 5(e) order at issue here is modified (or perhaps even revoked), would EPA “automatically” seek to amend or revoke the corresponding SNUR accordingly? As we discussed, as there are dozens of processors interested in the “new use” being sought, filing one or

more SNUNs is not workable. However, the PMN submitter/manufacturer could submit a request to amend or revoke the SNUR under 721.185(b)(1).

Thanks again – Tom

From: Berger, Tom C.

Sent: Wednesday, May 27, 2020 2:57 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: Ex. 4 CBI

Hi Jeff –

Thanks for taking the time to meet with us. Should we pencil in a time two weeks from now (i.e., June 9 or June 11) for our next call?

From: Bauer, Jeff <Bauer.Jeff@epa.gov>

Sent: Wednesday, May 13, 2020 1:32 PM

To: Berger, Tom C. <Berger@khlaw.com>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: Ex. 4 CBI

Tom,

I sent a meeting request to you three for May 27th at 2 p.m. to give a status update as requested.

Thanks

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

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Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>

Sent: Wednesday, May 13, 2020 12:53 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: Ex. 4 CBI

Hi Jeff –

Just seeing if it makes sense to set up a conference call in a week or two.

Thanks much again - Tom

From: Berger, Tom C.
Sent: Friday, May 8, 2020 11:14 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Jeff/Greg – thanks again.

Can/should we schedule a conference call with the submitter in a week or two?

Happy Friday!

Tom

From: Berger, Tom C.
Sent: Thursday, May 7, 2020 4:17 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: Re: **Ex. 4 CBI**

Jeff - thanks much.

Tom

On May 7, 2020, at 4:03 PM, Bauer, Jeff <Bauer.Jeff@epa.gov> wrote:

Tom, I hope you hanging in there as well, I have an email out to see if I can get a status update on the Assessor and to address you questions sent into CDX for a meeting.

Jeff

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

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Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Thursday, May 07, 2020 1:57 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff – Just touching base as the submitter has requested a status update.

Thanks again - Tom

From: Berger, Tom C.

Sent: Tuesday, May 5, 2020 11:56 AM

To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; 'Schweer, Greg' <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff – Just checking in on this – thanks - Tom

From: Berger, Tom C.

Sent: Wednesday, April 29, 2020 11:12 AM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I just thought I would check in on this and see if the Agency needs any additional information.

Thanks again and best regards,
Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com

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From: Berger, Tom C.

Sent: Thursday, April 23, 2020 7:13 PM

To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Jeff - thanks much.

Your recent voicemail and follow-up email indicated that the EPA Chemist has evaluated the study” on **Ex. 4 CBI** but that the reviewer did have a few questions and comments:

Ex. 4 CBI

To specifically answer the Chemist’s questions:

Ex. 4 CBI

Ex. 4 CBI

* * *

We trust that you find this information useful in resolved all outstanding issues. As always, if you have any questions please do not hesitate to contact us.

Best regards,
Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Tuesday, April 21, 2020 5:17 PM
To: Daniels, Rhys G. <daniels@khlaw.com>; Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: **Ex. 4 CBI**

I am moving forward with the review based on the information I have on the two studies, I wanted to share with you her comments on the test. **Ex. 4 CBI**

Ex. 4 CBI RAD has the
information and I am trying to get them to do the risk assessment based on **Ex. 4 CBI**

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

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1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Daniels, Rhys G. <daniels@khlaw.com>
Sent: Tuesday, April 21, 2020 4:58 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: **Ex. 4 CBI**

Jeff,

As always, we hope that all is well.

Per your recent voicemail and follow-up email concerning the **Ex. 4 CBI** case, we understand that the chemist has two questions concerning **Ex. 4 CBI**

Ex. 4 CBI

Thanks in advance for your response.

Rhys G. Daniels, Ph.D.
Staff Scientist
tel: +1 202.434.4270 | fax: +1 202.434.4646 | daniels@khlaw.com
1001 G Street NW, Suite 500 West | Washington, DC 20001

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Thursday, April 16, 2020 1:02 PM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: **Ex. 4 CBI**

Tom,

The chemist sent me a memo **Ex. 4 CBI** and they had two questions, I called and left you a message today **Ex. 4 CBI** I sent RAD a request last week to update the HH assessment **Ex. 4 CBI** as in my April 4, 2020 email to you. I have two emails into RAD on this case and will try an update you again in a week or so. I requested RAD set up a date with me to have a meeting to discuss how to proceed with this PMN.

Thanks
Jeff

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

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Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Thursday, April 16, 2020 12:28 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope that all is well.

Just checking in re status update. A non-CBI-containing email from you would probably be the best (if needed at some later time we can use EPA's new CBI via email authorization form if the submitter agrees).

Thanks again – Tom

From: Berger, Tom C.
Sent: Wednesday, April 8, 2020 11:06 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Jeff – thanks much for the update. Hope you and all at EPA are staying safe.

Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, April 8, 2020 11:03 AM
To: Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom,

Ex. 4 CBI

I will follow up with you next wed with a status update.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)

New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

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1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Wednesday, April 08, 2020 10:48 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>
Subject: RE: Ex. 4 CBI

Hi Greg –

I was just going through my to-do list and thought I would circle back on these two cases. I hope everyone is hanging in there.

Thanks again – Tom

From: Berger, Tom C.
Sent: Monday, March 30, 2020 3:46 PM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>
Subject: RE: Ex. 4 CBI

Greg / all – completely understood – thank you so much.

Tom

From: Schweer, Greg <Schweer.Greg@epa.gov>
Sent: Monday, March 30, 2020 3:42 PM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>
Subject: RE: Ex. 4 CBI

Hi Tom.

I am not ignoring you. I did check with Jeff Bauer early last week on this case. He filled me in on the requests he had made of RAD to review submitted test data and your request for a meeting. However, believe it or not, we have been having issues reliably being able to access our CBI-secure LAN. This hampers our ability to efficiently complete work. I will check on the status of your case as soon as I can.

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Monday, March 30, 2020 11:51 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: Ex. 4 CBI

Hi Greg –

Hope all is well.

Just thought I would check in with you on the **Ex. 4 CBI** LVEA (Lauren Davis) and **Ex. 4 CBI** with Jeff Bauer.

Thanks all always - Tom

From: Berger, Tom C.
Sent: Tuesday, March 24, 2020 11:12 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Greg – thanks so much as always. I also have an LVE with Lauren Davis **Ex. 4 CBI** held up in the process. Lauren has been responsive but the case has stalled (again, however, I understand the challenges you are facing).

These are my two “priority” cases.

Tom

From: Schweer, Greg <Schweer.Greg@epa.gov>
Sent: Tuesday, March 24, 2020 11:07 AM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: Re: **Ex. 4 CBI**

Tom,

Yes, things are a bit crazy. I will check into the case status today or tomorrow.

Sent from my iPhone

On Mar 24, 2020, at 10:48 AM, Berger, Tom C. <Berger@khlaw.com> wrote:

Hi Greg –

Obviously things are crazy and I don't want to push Jeff too hard but no response from Jeff on this case for a month.

Hang in there....

Tom

From: Berger, Tom C.
Sent: Monday, March 23, 2020 6:22 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies – just want to make sure you are getting these emails. Understand if there are delays.

Tom

From: Berger, Tom C.

Sent: Thursday, March 19, 2020 5:22 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff – checking in again – thanks - Tom

From: Berger, Tom C.

Sent: Monday, March 16, 2020 1:40 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I know things are crazy but checking in again – thanks - Tom

From: Berger, Tom C.

Sent: Wednesday, March 11, 2020 3:43 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Checking in again - thanks

From: Berger, Tom C.

Sent: Friday, March 6, 2020 1:33 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

The submitter is quite anxious – can we touch base next week?

Thanks much - Tom

From: Berger, Tom C.

Sent: Tuesday, February 25, 2020 9:08 AM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just checking in on this – thanks - Tom

From: Berger, Tom C.
Sent: Thursday, February 20, 2020 12:18 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope that all is well.

Per our discussions, the submitter has modified the questions to focus on toxicity/risk issues and submitted them via CDX yesterday. Can we start looking at conference call dates the week of March 9?

Thanks and best regards,
Tom

Thomas C. Berger
Partner
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From: Berger, Tom C.
Sent: Wednesday, January 29, 2020 11:41 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies we keep playing phone tag – can we discuss how to convert the below questions into questions that would be acceptable to RAD so we can schedule a call with you and RAD? Your voicemail suggested the below are more legal/regulatory than risk-based questions. We still need the below questions answered – perhaps we tee up the

more scientific ones for RAD then have the call to address both types of questions. The submitter is under growing commercial pressure.

Thanks much again - Tom

From: Berger, Tom C.
Sent: Monday, January 20, 2020 3:50 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies that we could not connect last week. Let's try to touch base tomorrow (Tuesday) if possible to discuss how to move this forward.

Thanks again – Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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From: Berger, Tom C.
Sent: Monday, January 13, 2020 2:50 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**
Importance: High

Hi Jeff –

Following is the list of questions we are considering submitting through CDX. Please let me know if these look ok.

Thanks again and best regards,
Tom

* * *

(1) Based on review of the submitted physical-chemical properties test data, does EPA now agree that use **Ex. 4 CBI** as described in

the PMN poses no unreasonable risk of injury and so plans to revoke the consent order?

(2) If so, what is the process for revoking the current consent order? Does the submitter now need to request that EPA revoke the order, or will EPA itself initiate revocation? What is the expected timing for revocation? How would EPA communicate such revocation?

(3) How would revocation of the consent order impact the final SNUR for the subject substance?

(4) Would a SNUN be a more expedient approach?

* * *

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, January 8, 2020 8:56 AM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: Ex. 4 CBI

Tom, I am expecting information from the engineer today or tomorrow on the Ex. 4 CBI test, I left you a message. There is a new procedure for us to set up meeting with RAD. I am to have the submitter send in a list of questions for RAD, they will assign someone up there as a Lead person who has two weeks and will set a date for when we can have a meeting. This may be our best route to other than just me bugging them to get things done. There were a series of emails on this case last week but now everyone is back from the holidays I am trying to get this case moving again.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

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Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Tuesday, January 07, 2020 4:16 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: Ex. 4 CBI

Hi Jeff –

I hope you had a great holiday! The client was wondering if we could have a conference call on this, this week or next. Please advise.

Thanks much – Tom

Thomas C. Berger
Partner

tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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From: Berger, Tom C.
Sent: Tuesday, December 10, 2019 2:10 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just checking back in – thanks - Tom

From: Berger, Tom C.
Sent: Thursday, December 5, 2019 9:46 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

When we spoke before Thanksgiving (I hope you had a great one!) you indicated that the reports were being reviewed and that I should reach out to you in early December.

Is there any update?

Thanks much and best regards – Tom

Thomas C. Berger
Partner

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From: Berger, Tom C.
Sent: Monday, November 18, 2019 1:17 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

The PMN submitter asked me to reach out to you to see if we can schedule a conference call (including EPA, K&H, and the submitter) on this case re status and pathforward.

Thanks - Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Friday, March 29, 2019 5:43 PM
To: Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom,
I set the meeting up for Wednesday April 3, at 11 am. RAD has accepted the invitation for that time.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

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Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Bauer, Jeff
Sent: Tuesday, March 26, 2019 11:37 AM
To: 'Berger, Tom C.' <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom, I left you a voice message, I am seeing what time it best for RAD to be part of the call.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

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1201 Constitution Ave., NW
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Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Tuesday, March 26, 2019 11:30 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi folks –

Just thought I would check in with you on this.

Thanks again - Tom

From: Berger, Tom C.
Sent: Friday, March 22, 2019 2:12 PM
To: 'Bauer.jeff@Epa.gov' <Bauer.jeff@Epa.gov>; 'Schweer, Greg' <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: **Ex. 4 CBI**

Hi folks –

I hope you are doing well. Jeff – this is the PMN case that my colleague, Dr. Rhys Daniels, spoke with you about earlier this week.

The issue is development of data needed to amend the existing section 5(e) order for this substance to add an additional use, and EPA approval of protocols for same. Would the Agency be available for a short conference call on this on one of the following days?:

- March 27 (except 12-2 ET)
- April 2
- April 3
- April 4

This is becoming more urgent from a commercial standpoint.

Thanks much - Tom

Thomas C. Berger
Partner
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Message

From: Berger, Tom C. [Berger@khlaw.com]
Sent: 6/1/2020 9:55:04 PM
To: Bauer, Jeff [Bauer.Jeff@epa.gov]; Alwood, Jim [Alwood.Jim@epa.gov]; Moss, Kenneth [Moss.Kenneth@epa.gov]
CC: Price, Amanda [price@khlaw.com]; Schweer, Greg [Schweer.Greg@epa.gov]; Daniels, Rhys G. [daniels@khlaw.com]; Edelstein, Rebecca [Edelstein.Rebecca@epa.gov]
Subject: RE: **Ex. 4 CBI**

Hi folks –

I hope you had a great weekend!

Just checking in on:

- (1) Scheduling a call on the 5(e)/SNUR case at issue; and
- (2) The issue of whether when a section 5(e) order is modified or revoked, does EPA “automatically” seek to amend or revoke the corresponding SNUR accordingly?

Thanks all - Tom

From: Berger, Tom C.
Sent: Thursday, May 28, 2020 12:23 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>; alwood.jim@epa.gov; Moss, Kenneth <Moss.Kenneth@epa.gov>; Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just following up on this.

Also (and I am cc'ing Jim Alwood and Ken Moss), per our discussions, if and when the section 5(e) order at issue here is modified (or perhaps even revoked), would EPA “automatically” seek to amend or revoke the corresponding SNUR accordingly? As we discussed, as there are dozens of processors interested in the “new use” being sought, filing one or more SNUNs is not workable. However, the PMN submitter/manufacture could submit a request to amend or revoke the SNUR under 721.185(b)(1).

Thanks again – Tom

From: Berger, Tom C.
Sent: Wednesday, May 27, 2020 2:57 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Thanks for taking the time to meet with us. Should we pencil in a time two weeks from now (i.e., June 9 or June 11) for our next call?

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, May 13, 2020 1:32 PM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom,

I sent a meeting request to you three for May 27th at 2 p.m. to give a status update as requested.

Thanks

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

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Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Wednesday, May 13, 2020 12:53 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just seeing if it makes sense to set up a conference call in a week or two.

Thanks much again - Tom

From: Berger, Tom C.
Sent: Friday, May 8, 2020 11:14 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Jeff/Greg – thanks again.

Can/should we schedule a conference call with the submitter in a week or two?

Happy Friday!

Tom

From: Berger, Tom C.
Sent: Thursday, May 7, 2020 4:17 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: Re: **Ex. 4 CBI**

Jeff - thanks much.

Tom

On May 7, 2020, at 4:03 PM, Bauer, Jeff <Bauer.Jeff@epa.gov> wrote:

Tom, I hope you hanging in there as well, I have an email out to see if I can get a status update on the Assessor and to address you questions sent into CDX for a meeting.

Jeff

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

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1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Thursday, May 07, 2020 1:57 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff – Just touching base as the submitter has requested a status update.

Thanks again - Tom

From: Berger, Tom C.
Sent: Tuesday, May 5, 2020 11:56 AM
To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; 'Schweer, Greg' <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff – Just checking in on this – thanks - Tom

From: Berger, Tom C.

Sent: Wednesday, April 29, 2020 11:12 AM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I just thought I would check in on this and see if the Agency needs any additional information.

Thanks again and best regards,

Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com

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From: Berger, Tom C.

Sent: Thursday, April 23, 2020 7:13 PM

To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Jeff - thanks much.

Your recent voicemail and follow-up email indicated that the EPA Chemist has evaluated the study” on **Ex. 4 CBI** but that the reviewer did have a few questions and comments: **Ex. 4 CBI**

Ex. 4 CBI

Ex. 4 CBI

To specifically answer the Chemist's questions:

Ex. 4 CBI

Ex. 4 CBI

* * *

We trust that you find this information useful in resolved all outstanding issues. As always, if you have any questions please do not hesitate to contact us.

Best regards,
Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Tuesday, April 21, 2020 5:17 PM
To: Daniels, Rhys G. <daniels@khlaw.com>; Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: **Ex. 4 CBI**

I am moving forward with the review based on the information I have on the two studies, I wanted to share with you her comments on the test. **Ex. 4 CBI**

Ex. 4 CBI RAD has the information and I am trying to get them to do the risk assessment based on **Ex. 4 CBI**

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

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1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Daniels, Rhys G. <daniels@khlaw.com>
Sent: Tuesday, April 21, 2020 4:58 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: **Ex. 4 CBI**

Jeff,

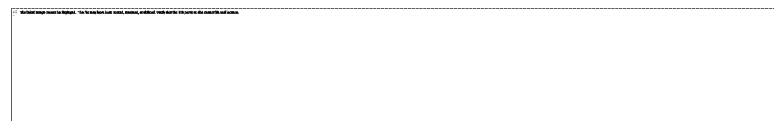
As always, we hope that all is well.

Per your recent voicemail and follow-up email concerning the **Ex. 4 CBI** case, we understand that the chemist has two questions concerning **Ex. 4 CBI**

Ex. 4 CBI

Thanks in advance for your response.

Rhys G. Daniels, Ph.D.
Staff Scientist
tel: +1 202.434.4270 | fax: +1 202.434.4646 | daniels@khlaw.com
1001 G Street NW, Suite 500 West | Washington, DC 20001



From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Thursday, April 16, 2020 1:02 PM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: **Ex. 4 CBI**

Tom,

The chemist sent me a memo **Ex. 4 CBI** and they had two questions, I called and left you a message today **Ex. 4 CBI**. I sent RAD a request last week to update the HH assessment **Ex. 4 CBI** as in my April 4, 2020 email to you. I have two emails into RAD on this case and will try an update you again in a week or so. I requested RAD set up a date with me to have a meeting to discuss how to proceed with this PMN.

Thanks
Jeff

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

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1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Thursday, April 16, 2020 12:28 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope that all is well.

Just checking in re status update. A non-CBI-containing email from you would probably be the best (if needed at some later time we can use EPA's new CBI via email authorization form if the submitter agrees).

Thanks again – Tom

From: Berger, Tom C.
Sent: Wednesday, April 8, 2020 11:06 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Jeff – thanks much for the update. Hope you and all at EPA are staying safe.

Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, April 8, 2020 11:03 AM
To: Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom,

Ex. 4 CBI

I will follow up with you next wed with a status update.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

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Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Wednesday, April 08, 2020 10:48 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Greg –

I was just going through my to-do list and thought I would circle back on these two cases. I hope everyone is hanging in there.

Thanks again – Tom

From: Berger, Tom C.
Sent: Monday, March 30, 2020 3:46 PM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Greg / all – completely understood – thank you so much.

Tom

From: Schweer, Greg <Schweer.Greg@epa.gov>
Sent: Monday, March 30, 2020 3:42 PM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>
Subject: RE: **Ex. 4 CBI**

Hi Tom.

I am not ignoring you. I did check with Jeff Bauer early last week on this case. He filled me in on the requests he had made of RAD to review submitted test data and your request for a meeting. However, believe it or not, we have been having issues reliably being able to access our CBI-secure LAN. This hampers our ability to efficiently complete work. I will check on the status of your case as soon as I can.

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Monday, March 30, 2020 11:51 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Greg –

Hope all is well.

Just thought I would check in with you on the **Ex. 4 CBI** LVEA (Lauren Davis) and **Ex. 4 CBI** **Ex. 4 CBI** with Jeff Bauer.

Thanks all always - Tom

From: Berger, Tom C.
Sent: Tuesday, March 24, 2020 11:12 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Greg – thanks so much as always. I also have an LVE with Lauren Davis:

Ex. 4 CBI

Ex. 4 CBI held up in the process. Lauren has been responsive but the case has stalled (again, however, I understand the challenges you are facing).

These are my two “priority” cases.

Tom

From: Schweer, Greg <Schweer.Greg@epa.gov>

Sent: Tuesday, March 24, 2020 11:07 AM

To: Berger, Tom C. <Berger@khlaw.com>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: Re: **Ex. 4 CBI**

Tom,

Yes, things are a bit crazy. I will check into the case status today or tomorrow.

Sent from my iPhone

On Mar 24, 2020, at 10:48 AM, Berger, Tom C. <Berger@khlaw.com> wrote:

Hi Greg –

Obviously things are crazy and I don’t want to push Jeff too hard but no response from Jeff on this case for a month.

Hang in there....

Tom

From: Berger, Tom C.

Sent: Monday, March 23, 2020 6:22 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies – just want to make sure you are getting these emails. Understand if there are delays.

Tom

From: Berger, Tom C.

Sent: Thursday, March 19, 2020 5:22 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff – checking in again – thanks - Tom

From: Berger, Tom C.
Sent: Monday, March 16, 2020 1:40 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I know things are crazy but checking in again – thanks - Tom

From: Berger, Tom C.
Sent: Wednesday, March 11, 2020 3:43 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Checking in again - thanks

From: Berger, Tom C.
Sent: Friday, March 6, 2020 1:33 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

The submitter is quite anxious – can we touch base next week?

Thanks much - Tom

From: Berger, Tom C.
Sent: Tuesday, February 25, 2020 9:08 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just checking in on this – thanks - Tom

From: Berger, Tom C.
Sent: Thursday, February 20, 2020 12:18 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope that all is well.

Per our discussions, the submitter has modified the questions to focus on toxicity/risk issues and submitted them via CDX yesterday. Can we start looking at conference call dates the week of March 9?

Thanks and best regards,
Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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From: Berger, Tom C.
Sent: Wednesday, January 29, 2020 11:41 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies we keep playing phone tag – can we discuss how to convert the below questions into questions that would be acceptable to RAD so we can schedule a call with you and RAD? Your voicemail suggested the below are more legal/regulatory than risk-based questions. We still need the below questions answered – perhaps we tee up the more scientific ones for RAD then have the call to address both types of questions. The submitter is under growing commercial pressure.

Thanks much again - Tom

From: Berger, Tom C.
Sent: Monday, January 20, 2020 3:50 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies that we could not connect last week. Let's try to touch base tomorrow (Tuesday) if possible to discuss how to move this forward.

Thanks again – Tom

Thomas C. Berger
Partner

tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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From: Berger, Tom C.
Sent: Monday, January 13, 2020 2:50 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**
Importance: High

Hi Jeff –

Following is the list of questions we are considering submitting through CDX. Please let me know if these look ok.

Thanks again and best regards,
Tom

* * *

*(1) Based on review of the submitted physical-chemical properties test data, does EPA now agree that use of **Ex. 4 CBI** as described in the PMN poses no unreasonable risk of injury and so plans to revoke the consent order?*

(2) If so, what is the process for revoking the current consent order? Does the submitter now need to request that EPA revoke the order, or will EPA itself initiate revocation? What is the expected timing for revocation? How would EPA communicate such revocation?

(3) How would revocation of the consent order impact the final SNUR for the subject substance?

(4) Would a SNUN be a more expedient approach?

* * *

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, January 8, 2020 8:56 AM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom, I am expecting information from the engineer today or tomorrow on the **Ex. 4 CBI** test. I left you a message. There is a new procedure for us to set up meeting with RAD. I am to have the submitter send in a list of questions for RAD, they will assign someone up there as a Lead person who has two weeks and will set a date for when we can have a meeting. This may be our best route to other than just me bugging them to get things done. There were a series of emails on this case last week but now everyone is back from the holidays I am trying to get this case moving again.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

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1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Tuesday, January 07, 2020 4:16 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope you had a great holiday! The client was wondering if we could have a conference call on this, this week or next. Please advise.

Thanks much – Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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From: Berger, Tom C.
Sent: Tuesday, December 10, 2019 2:10 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just checking back in – thanks - Tom

From: Berger, Tom C.
Sent: Thursday, December 5, 2019 9:46 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

When we spoke before Thanksgiving (I hope you had a great one!) you indicated that the reports were being reviewed and that I should reach out to you in early December.

Is there any update?

Thanks much and best regards – Tom

Thomas C. Berger
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From: Berger, Tom C.
Sent: Monday, November 18, 2019 1:17 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

The PMN submitter asked me to reach out to you to see if we can schedule a conference call (including EPA, K&H, and the submitter) on this case re status and pathforward.

Thanks - Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Friday, March 29, 2019 5:43 PM
To: Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom,
I set the meeting up for Wednesday April 3, at 11 am. RAD has accepted the invitation for that time.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

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1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Bauer, Jeff
Sent: Tuesday, March 26, 2019 11:37 AM
To: 'Berger, Tom C.' <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom, I left you a voice message, I am seeing what time it best for RAD to be part of the call.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

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Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Tuesday, March 26, 2019 11:30 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi folks –

Just thought I would check in with you on this.

Thanks again - Tom

From: Berger, Tom C.
Sent: Friday, March 22, 2019 2:12 PM
To: 'Bauer.jeff@Epa.gov' <Bauer.jeff@Epa.gov>; 'Schweer, Greg' <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: **Ex. 4 CBI**

Hi folks –

I hope you are doing well. Jeff – this is the PMN case that my colleague, Dr. Rhys Daniels, spoke with you about earlier this week.

The issue is development of data needed to amend the existing section 5(e) order for this substance to add an additional use, and EPA approval of protocols for same. Would the Agency be available for a short conference call on this on one of the following days?:

- March 27 (except 12-2 ET)
- April 2
- April 3
- April 4

This is becoming more urgent from a commercial standpoint.

Thanks much - Tom

Thomas C. Berger
Partner
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Message

From: Berger, Tom C. [Berger@khlaw.com]
Sent: 5/28/2020 4:23:18 PM
To: Bauer, Jeff [Bauer.Jeff@epa.gov]
CC: Price, Amanda [price@khlaw.com]; Schweer, Greg [Schweer.Greg@epa.gov]; Daniels, Rhys G. [daniels@khlaw.com]; Alwood, Jim [Alwood.Jim@epa.gov]; Moss, Kenneth [Moss.Kenneth@epa.gov]; Edelstein, Rebecca [Edelstein.Rebecca@epa.gov]
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just following up on this.

Also (and I am cc'ing Jim Alwood and Ken Moss), per our discussions, if and when the section 5(e) order at issue here is modified (or perhaps even revoked), would EPA “automatically” seek to amend or revoke the corresponding SNUR accordingly? As we discussed, as there are dozens of processors interested in the “new use” being sought, filing one or more SNUNs is not workable. However, the PMN submitter/manufacture could submit a request to amend or revoke the SNUR under 721.185(b)(1).

Thanks again – Tom

From: Berger, Tom C.
Sent: Wednesday, May 27, 2020 2:57 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Thanks for taking the time to meet with us. Should we pencil in a time two weeks from now (i.e., June 9 or June 11) for our next call?

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, May 13, 2020 1:32 PM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom,

I sent a meeting request to you three for May 27th at 2 p.m. to give a status update as requested.

Thanks

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)

<http://www.epa.gov/oppt/newchemicals/>

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Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Wednesday, May 13, 2020 12:53 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just seeing if it makes sense to set up a conference call in a week or two.

Thanks much again - Tom

From: Berger, Tom C.
Sent: Friday, May 8, 2020 11:14 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Jeff/Greg – thanks again.

Can/should we schedule a conference call with the submitter in a week or two?

Happy Friday!

Tom

From: Berger, Tom C.
Sent: Thursday, May 7, 2020 4:17 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: Re: **Ex. 4 CBI**

Jeff - thanks much.

Tom

On May 7, 2020, at 4:03 PM, Bauer, Jeff <Bauer.Jeff@epa.gov> wrote:

Tom, I hope you hanging in there as well, I have an email out to see if I can get a status update on the Assessor and to address your questions sent into CDX for a meeting.

Jeff

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Thursday, May 07, 2020 1:57 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff – Just touching base as the submitter has requested a status update.

Thanks again - Tom

From: Berger, Tom C.
Sent: Tuesday, May 5, 2020 11:56 AM
To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; 'Schweer, Greg' <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff – Just checking in on this – thanks - Tom

From: Berger, Tom C.
Sent: Wednesday, April 29, 2020 11:12 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I just thought I would check in on this and see if the Agency needs any additional information.

Thanks again and best regards,
Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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From: Berger, Tom C.

Sent: Thursday, April 23, 2020 7:13 PM

To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Jeff - thanks much.

Your recent voicemail and follow-up email indicated that the EPA Chemist has evaluated the study" on **Ex. 4 CBI** but that the reviewer did have a few questions and comments: **Ex. 4 CBI**

Ex. 4 CBI

Ex. 4 CBI

To specifically answer the Chemist's questions:

Ex. 4 CBI

Ex. 4 CBI

We trust that you find this information useful in resolved all outstanding issues. As always, if you have any questions please do not hesitate to contact us.

Best regards,
Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Tuesday, April 21, 2020 5:17 PM
To: Daniels, Rhys G. <daniels@khlaw.com>; Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: **Ex. 4 CBI**

I am moving forward with the review based on the information I have on the two studies, I wanted to share with you her comments on the test. **Ex. 4 CBI**

Ex. 4 CBI RAD has the
information and I am trying to get them to do the risk assessment based on **Ex. 4 CBI**

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)

Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

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1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Daniels, Rhys G. <daniels@khlaw.com>
Sent: Tuesday, April 21, 2020 4:58 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: **Ex. 4 CBI**

Jeff,

As always, we hope that all is well.

Per your recent voicemail and follow-up email concerning the **Ex. 4 CBI** case, we understand that the chemist has two questions concerning **Ex. 4 CBI**

Ex. 4 CBI

Thanks in advance for your response.

Rhys G. Daniels, Ph.D.
Staff Scientist
tel: +1 202.434.4270 | fax: +1 202.434.4646 | daniels@khlaw.com
1001 G Street NW, Suite 500 West | Washington, DC 20001

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Thursday, April 16, 2020 1:02 PM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: **Ex. 4 CBI**

Tom,

The chemist sent me a memo [Ex. 4 CBI] and they had two questions, I called and left you a message today [Ex. 4 CBI] I sent RAD a request last week to update the HH assessment [Ex. 4 CBI] as in my April 4, 2020 email to you. I have two emails into RAD on this case and will try an update you again in a week or so. I requested RAD set up a date with me to have a meeting to discuss how to proceed with this PMN.

Thanks
Jeff

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

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1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Thursday, April 16, 2020 12:28 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: [Ex. 4 CBI]

Hi Jeff –

I hope that all is well.

Just checking in re status update. A non-CBI-containing email from you would probably be the best (if needed at some later time we can use EPA's new CBI via email authorization form if the submitter agrees).

Thanks again – Tom

From: Berger, Tom C.
Sent: Wednesday, April 8, 2020 11:06 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>
Subject: RE: [Ex. 4 CBI]

Jeff – thanks much for the update. Hope you and all at EPA are staying safe.

Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, April 8, 2020 11:03 AM
To: Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom,

Ex. 4 CBI

I will follow up with you next wed with a status update.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

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Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Wednesday, April 08, 2020 10:48 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Greg –

I was just going through my to-do list and thought I would circle back on these two cases. I hope everyone is hanging in there.

Thanks again – Tom

From: Berger, Tom C.
Sent: Monday, March 30, 2020 3:46 PM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Greg / all – completely understood – thank you so much.

Tom

From: Schweer, Greg <Schweer.Greg@epa.gov>
Sent: Monday, March 30, 2020 3:42 PM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>
Subject: RE: **Ex. 4 CBI**

Hi Tom.

I am not ignoring you. I did check with Jeff Bauer early last week on this case. He filled me in on the requests he had made of RAD to review submitted test data and your request for a meeting. However, believe it or not, we have been having issues reliably being able to access our CBI-secure LAN. This hampers our ability to efficiently complete work. I will check on the status of your case as soon as I can.

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Monday, March 30, 2020 11:51 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Greg –

Hope all is well.

Just thought I would check in with you on the **Ex. 4 CBI** LVEA (Lauren Davis) and **Ex. 4 CBI** **Ex. 4 CBI** with Jeff Bauer.

Thanks all always - Tom

From: Berger, Tom C.
Sent: Tuesday, March 24, 2020 11:12 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Greg – thanks so much as always. I also have an LVE with Lauren Davis **Ex. 4 CBI** **Ex. 4 CBI** held up in the process. Lauren has been responsive but the case has stalled (again, however, I understand the challenges you are facing).

These are my two “priority” cases.

Tom

From: Schweer, Greg <Schweer.Greg@epa.gov>
Sent: Tuesday, March 24, 2020 11:07 AM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: Re: **Ex. 4 CBI**

Tom,

Yes, things are a bit crazy. I will check into the case status today or tomorrow.

Sent from my iPhone

On Mar 24, 2020, at 10:48 AM, Berger, Tom C. <Berger@khlaw.com> wrote:

Hi Greg –

Obviously things are crazy and I don't want to push Jeff too hard but no response from Jeff on this case for a month.

Hang in there....

Tom

From: Berger, Tom C.
Sent: Monday, March 23, 2020 6:22 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies – just want to make sure you are getting these emails. Understand if there are delays.

Tom

From: Berger, Tom C.
Sent: Thursday, March 19, 2020 5:22 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff – checking in again – thanks - Tom

From: Berger, Tom C.
Sent: Monday, March 16, 2020 1:40 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I know things are crazy but checking in again – thanks - Tom

From: Berger, Tom C.
Sent: Wednesday, March 11, 2020 3:43 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Checking in again - thanks

From: Berger, Tom C.
Sent: Friday, March 6, 2020 1:33 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

The submitter is quite anxious – can we touch base next week?

Thanks much - Tom

From: Berger, Tom C.
Sent: Tuesday, February 25, 2020 9:08 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just checking in on this – thanks - Tom

From: Berger, Tom C.
Sent: Thursday, February 20, 2020 12:18 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope that all is well.

Per our discussions, the submitter has modified the questions to focus on toxicity/risk issues and submitted them via CDX yesterday. Can we start looking at conference call dates the week of March 9?

Thanks and best regards,
Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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From: Berger, Tom C.
Sent: Wednesday, January 29, 2020 11:41 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies we keep playing phone tag – can we discuss how to convert the below questions into questions that would be acceptable to RAD so we can schedule a call with you and RAD? Your voicemail suggested the below are more legal/regulatory than risk-based questions. We still need the below questions answered – perhaps we tee up the more scientific ones for RAD then have the call to address both types of questions. The submitter is under growing commercial pressure.

Thanks much again - Tom

From: Berger, Tom C.
Sent: Monday, January 20, 2020 3:50 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies that we could not connect last week. Let's try to touch base tomorrow (Tuesday) if possible to discuss how to move this forward.

Thanks again – Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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From: Berger, Tom C.
Sent: Monday, January 13, 2020 2:50 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**
Importance: High

Hi Jeff –

Following is the list of questions we are considering submitting through CDX. Please let me know if these look ok.

Thanks again and best regards,
Tom

* * *

*(1) Based on review of the submitted physical-chemical properties test data, does EPA now agree that use **Ex. 4 CBI** as described in the PMN poses no unreasonable risk of injury and so plans to revoke the consent order?*

(2) If so, what is the process for revoking the current consent order? Does the submitter now need to request that EPA revoke the order, or will EPA itself initiate revocation? What is the expected timing for revocation? How would EPA communicate such revocation?

(3) How would revocation of the consent order impact the final SNUR for the subject substance?

(4) Would a SNUN be a more expedient approach?

* * *

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, January 8, 2020 8:56 AM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom, I am expecting information from the engineer today or tomorrow on the **Ex. 4 CBI** test, I left you a message. There is a new procedure for us to set up meeting with RAD. I am to have the submitter send in a list of questions for RAD, they will assign someone up there as a Lead person who has two weeks and will set a date for when we can have a meeting. This may be our best route to other than just me bugging them to get things done. There were a series of emails on this case last week but now everyone is back from the holidays I am trying to get this case moving again.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)

<http://www.epa.gov/oppt/newchems/>

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Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Tuesday, January 07, 2020 4:16 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope you had a great holiday! The client was wondering if we could have a conference call on this, this week or next. Please advise.

Thanks much – Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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From: Berger, Tom C.
Sent: Tuesday, December 10, 2019 2:10 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just checking back in – thanks - Tom

From: Berger, Tom C.
Sent: Thursday, December 5, 2019 9:46 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

When we spoke before Thanksgiving (I hope you had a great one!) you indicated that the reports were being reviewed and that I should reach out to you in early December.

Is there any update?

Thanks much and best regards – Tom

Thomas C. Berger

Partner

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From: Berger, Tom C.
Sent: Monday, November 18, 2019 1:17 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

The PMN submitter asked me to reach out to you to see if we can schedule a conference call (including EPA, K&H, and the submitter) on this case re status and pathforward.

Thanks - Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Friday, March 29, 2019 5:43 PM
To: Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom,
I set the meeting up for Wednesday April 3, at 11 am. RAD has accepted the invitation for that time.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

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1201 Constitution Ave., NW

Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Bauer, Jeff
Sent: Tuesday, March 26, 2019 11:37 AM
To: 'Berger, Tom C.' <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom, I left you a voice message, I am seeing what time it best for RAD to be part of the call.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Tuesday, March 26, 2019 11:30 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi folks –

Just thought I would check in with you on this.

Thanks again - Tom

From: Berger, Tom C.
Sent: Friday, March 22, 2019 2:12 PM
To: 'Bauer.jeff@Epa.gov' <Bauer.jeff@Epa.gov>; 'Schweer, Greg' <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: **Ex. 4 CBI**

Hi folks –

I hope you are doing well. Jeff – this is the PMN case that my colleague, Dr. Rhys Daniels, spoke with you about earlier this week.

The issue is development of data needed to amend the existing section 5(e) order for this substance to add an additional use, and EPA approval of protocols for same. Would the Agency be available for a short conference call on this on one of the following days?:

- March 27 (except 12-2 ET)
- April 2
- April 3
- April 4

This is becoming more urgent from a commercial standpoint.

Thanks much - Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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Message

From: Schutz, David [Schutz.David@epa.gov]
Sent: 5/27/2020 6:58:28 PM
To: lee.french@dupont.com
CC: Edelstein, Rebecca [Edelstein.Rebecca@epa.gov]; Schweer, Greg [Schweer.Greg@epa.gov]; Victor, Meg [Victor.Meg@epa.gov]; Stanton, Alexandria [stanton.alexandria@epa.gov]; Miller, Monica [miller.monica@epa.gov]; Tierney, Meghan [Tierney.Meghan@epa.gov]
Subject: FW: LVE intake question

Mr. French, Greg Schweer has asked me to get back to you – let me know if I am missing anything since I was not in on the beginning of this discussion. 40 CFR 720.45(g) directs that the submitter provide information on ‘manufacture’ site. A kind of confusing aspect of the TSCA is that it defines ‘import’ as equivalent to ‘manufacture’ (40 CFR 720.3(q) Manufacture means to produce or manufacture in the United States or import into the customs territory of the United States) and that results in the site of import being the site of manufacture for the purpose of Section 5 notices. I’m a bit puzzled about your statement that this information has never been required before, it should have been. As Greg Schweer noted, the responsibility has been recently given to the engineers in our sister division – but it would not have been my understanding that the requirement was new. Please feel free to get back to me if additional questions. Dave Schutz

From: French, Lee <lee.french@dupont.com>
Sent: Tuesday, May 26, 2020 8:47 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Tierney, Meghan <Tierney.Meghan@epa.gov>
Subject: RE: LVE intake question

Hello Greg,

I am having difficulty understanding why identification of the storage and distribution sites (where no manufacturing, processing, or use takes place and so there is no potential for exposure or release) would be required. Below, you cited the requirements of 720.45(g), but these distribution and storage sites (with the above qualification) do not seem to be included in the sites defined in 720.45(g).

I have never been asked to provide storage and distribution site information in past submissions. When was this change made to the information requirements? Was this policy change communicated? (I do not remember seeing anything.) Is there any guidance around the new policy?

We are going to need to discuss this policy change internally. I was hoping that this was just a misunderstanding or confusion on the part of the intake reviewer. But if this is in fact a new data requirement, that raises some concerns on our side. Could you share any information about why this change in data requirements was made?

Thanks,
Lee

From: Schweer, Greg <Schweer.Greg@epa.gov>
Sent: Tuesday, May 26, 2020 6:30 AM
To: French, Lee <lee.french@dupont.com>
Cc: Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Tierney, Meghan <Tierney.Meghan@epa.gov>
Subject: [EXTERNAL] Re: LVE intake question

Lee,

There is also the option to send only a notification (rather than an LVE modification request) to EPA that a new site is being used provided that the conditions in 40 CFR 723.50(j)(6) regarding exposure and releases are met.

From: Schweer, Greg

Sent: Friday, May 22, 2020 4:15 PM

To: French, Lee <lee.french@dupont.com>

Cc: Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Tierney, Meghan <Tierney.Meghan@epa.gov>

Subject: Re: LVE intake question

That is my understanding, Lee.

Sent from my iPhone

On May 22, 2020, at 4:06 PM, French, Lee <lee.french@dupont.com> wrote:

Thank you for the response Greg.

I would like to confirm that I am understanding these changes correctly.

For a NCS that is import only, all domestic storage and distribution sites under the control of the submitter must be identified in the LVE, even if there is no manufacturing, processing, or use activities (meaning there is no human exposure or environmental release) at the domestic storage/distribution sites?

And if we want to use a different storage/distribution site (again, there is no exposure or release at these sites) in the future, we would need to submit a LVE modification?

Is this correct?

Thank you for your time,
Lee French

From: Schweer, Greg <Schweer.Greg@epa.gov>

Sent: Friday, May 22, 2020 3:42 PM

To: French, Lee <lee.french@dupont.com>

Cc: Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>; Tierney, Meghan <Tierney.Meghan@epa.gov>

Subject: [EXTERNAL] Re: LVE intake question

Lee,

The engineers in the Risk Assessment Division have recently started to "pre-screen" new chemical notifications to identify information that should have been included in the notification per 720.45(g) and to notify the submitter of such missing information. For this case during RAD Prescreen, for import only scenarios, when it is not clear that there are no domestic storage/distribution sites for the NCS, RAD Prescreeners request that the Submitter identify any

such sites and operations at these sites or clearly indicate there are no such sites. So, I recommend that, if you know the identity of the site in question, then provide that info to EPA in an amendment to the LVE. If there is a need to change the site in the future, an LVE modification request can be submitted.

From: Schweer, Greg
Sent: Friday, May 22, 2020 11:29 AM
To: French, Lee <lee.french@dupont.com>
Cc: Edelstein, Rebecca <Edelstein.Rebecca@epa.gov>
Subject: Re: LVE intake question

Lee,

Ex. 6 Personal Privacy (PP)

did receive some information on this issue from our Risk Assessment Division. I will send you a more informative email when I get home.

Sent from my iPhone

On May 22, 2020, at 10:51 AM, French, Lee <lee.french@dupont.com> wrote:

Hi Greg,

I am following up on the email below.

What is the best way to resolve this situation? The LVE submission has now been help up over a month at intake. Anny assistance you could provide would be appreciated.

Thanks,

Lee French
PS&R TSCA Consultant
1801 Larkin Center Dr.,
Larkin Lab; Office 351
Midland, MI 48642

<image001.png>

Lee.French@dupont.com
www.dupont.com

From: French, Lee
Sent: Thursday, May 14, 2020 5:53 PM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Subject: LVE intake question

Hi Greg.

I have a LVE that is held up in the intake review process. The intake reviewer has told me that there has been a change in the information requirements and that I need to provide information that I normally would not include in the LVE submission. My understanding is that we now need to list 'sites controlled by submitter' even if there is no exposure or releases at the site. (e.g. for a 'import only' submission, we would need to list the site address of the warehouse that receives the import even if it is just a pass-through and there is no manufacture/processing/use activity at the site.)

Would you be available for a short phone conversation to clarify this new requirement? If so, can you provide a phone number, or call me at 989.859.6248?

Thank you,

Lee French
PS&R TSCA Consultant
1801 Larkin Center Dr.,
Larkin Lab; Office 351
Midland, MI 48642

<image001.png>

Lee.French@dupont.com
www.dupont.com

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Message

From: Berger, Tom C. [Berger@khlaw.com]
Sent: 5/27/2020 6:56:35 PM
To: Bauer, Jeff [Bauer.Jeff@epa.gov]
CC: Price, Amanda [price@khlaw.com]; Schweer, Greg [Schweer.Greg@epa.gov]; Daniels, Rhys G. [daniels@khlaw.com]
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Thanks for taking the time to meet with us. Should we pencil in a time two weeks from now (i.e., June 9 or June 11) for our next call?

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, May 13, 2020 1:32 PM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom,

I sent a meeting request to you three for May 27th at 2 p.m. to give a status update as requested.

Thanks

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Wednesday, May 13, 2020 12:53 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just seeing if it makes sense to set up a conference call in a week or two.

Thanks much again - Tom

From: Berger, Tom C.
Sent: Friday, May 8, 2020 11:14 AM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Jeff/Greg – thanks again.

Can/should we schedule a conference call with the submitter in a week or two?

Happy Friday!

Tom

From: Berger, Tom C.

Sent: Thursday, May 7, 2020 4:17 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: Re: **Ex. 4 CBI**

Jeff - thanks much.

Tom

On May 7, 2020, at 4:03 PM, Bauer, Jeff <Bauer.Jeff@epa.gov> wrote:

Tom, I hope you hanging in there as well, I have an email out to see if I can get a status update on the Assessor and to address you questions sent into CDX for a meeting.

Jeff

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>

Sent: Thursday, May 07, 2020 1:57 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff – Just touching base as the submitter has requested a status update.

Thanks again - Tom

From: Berger, Tom C.
Sent: Tuesday, May 5, 2020 11:56 AM
To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; 'Schweer, Greg' <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff – Just checking in on this – thanks - Tom

From: Berger, Tom C.
Sent: Wednesday, April 29, 2020 11:12 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I just thought I would check in on this and see if the Agency needs any additional information.

Thanks again and best regards,
Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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From: Berger, Tom C.
Sent: Thursday, April 23, 2020 7:13 PM
To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Jeff - thanks much.

Your recent voicemail and follow-up email indicated that the EPA Chemist has evaluated the study on **Ex. 4 CBI** but that the reviewer did have a few questions and comments:

Ex. 4 CBI

Ex. 4 CBI

Ex. 4 CBI

To specifically answer the Chemist's questions:

Ex. 4 CBI

Ex. 4 CBI

* * *

We trust that you find this information useful in resolved all outstanding issues. As always, if you have any questions please do not hesitate to contact us.

Best regards,
Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Tuesday, April 21, 2020 5:17 PM
To: Daniels, Rhys G. <daniels@khlaw.com>; Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: **Ex. 4 CBI**

I am moving forward with the review based on the information I have on the two studies, I wanted to share with you her comments on the test. **Ex. 4 CBI**

Ex. 4 CBI RAD has the information and I am trying to get them to do the risk assessment based on **Ex. 4 CBI**

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

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1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Daniels, Rhys G. <daniels@khlaw.com>
Sent: Tuesday, April 21, 2020 4:58 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: **Ex. 4 CBI**

Jeff,

As always, we hope that all is well.

Per your recent voicemail and follow-up email concerning the **Ex. 4 CBI** case, we understand that the chemist has two questions concerning **Ex. 4 CBI**

Ex. 4 CBI

Ex. 4 CBI

Thanks in advance for your response.

Rhys G. Daniels, Ph.D.

Staff Scientist

tel: +1 202.434.4270 | fax: +1 202.434.4646 | daniels@khlaw.com

1001 G Street NW, Suite 500 West | Washington, DC 20001



From: Bauer, Jeff <Bauer.Jeff@epa.gov>

Sent: Thursday, April 16, 2020 1:02 PM

To: Berger, Tom C. <Berger@khlaw.com>

Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>

Subject: RE: **Ex. 4 CBI**

Tom,

The chemist sent me a memo **Ex. 4 CBI** and they had two questions, I called and left you a message today **Ex. 4 CBI** I sent RAD a request last week to update the HH assessment **Ex. 4 CBI** as in my April 4, 2020 email to you. I have two emails into RAD on this case and will try an update you again in a week or so. I requested RAD set up a date with me to have a meeting to discuss how to proceed with this PMN.

Thanks

Jeff

Jeff Bauer - Program Manager

United States Environmental Protection Agency (USEPA)

Office of Pollution Prevention and Toxics (OPPT)

New Chemicals Program (7405M)

<http://www.epa.gov/oppt/newchemicals/>

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Washington, DC 20004

Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>

Sent: Thursday, April 16, 2020 12:28 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope that all is well.

Just checking in re status update. A non-CBI-containing email from you would probably be the best (if needed at some later time we can use EPA's new CBI via email authorization form if the submitter agrees).

Thanks again – Tom

From: Berger, Tom C.

Sent: Wednesday, April 8, 2020 11:06 AM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Jeff – thanks much for the update. Hope you and all at EPA are staying safe.

Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>

Sent: Wednesday, April 8, 2020 11:03 AM

To: Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Tom,

Ex. 4 CBI

I will follow up with you next wed with a status update.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

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Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Wednesday, April 08, 2020 10:48 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Greg –

I was just going through my to-do list and thought I would circle back on these two cases. I hope everyone is hanging in there.

Thanks again – Tom

From: Berger, Tom C.
Sent: Monday, March 30, 2020 3:46 PM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Greg / all – completely understood – thank you so much.

Tom

From: Schweer, Greg <Schweer.Greg@epa.gov>
Sent: Monday, March 30, 2020 3:42 PM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>
Subject: RE: **Ex. 4 CBI**

Hi Tom.

I am not ignoring you. I did check with Jeff Bauer early last week on this case. He filled me in on the requests he had made of RAD to review submitted test data and your request for a meeting. However, believe it or not, we have been having issues reliably being able to access our CBI-secure LAN. This hampers our ability to efficiently complete work. I will check on the status of your case as soon as I can.

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Monday, March 30, 2020 11:51 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Greg –

Hope all is well.

Just thought I would check in with you on the **Ex. 4 CBI** LVEA (Lauren Davis) and **Ex. 4 CBI** **Ex. 4 CBI** with Jeff Bauer.

Thanks all always - Tom

From: Berger, Tom C.
Sent: Tuesday, March 24, 2020 11:12 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Greg – thanks so much as always. I also have an LVE with Lauren Davis **Ex. 4 CBI** held up in the process. Lauren has been responsive but the case has stalled (again, however, I understand the challenges you are facing).

These are my two “priority” cases.

Tom

From: Schweer, Greg <Schweer.Greg@epa.gov>
Sent: Tuesday, March 24, 2020 11:07 AM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: Re: **Ex. 4 CBI**

Tom,

Yes, things are a bit crazy. I will check into the case status today or tomorrow.

Sent from my iPhone

On Mar 24, 2020, at 10:48 AM, Berger, Tom C. <Berger@khlaw.com> wrote:

Hi Greg –

Obviously things are crazy and I don't want to push Jeff too hard but no response from Jeff on this case for a month.

Hang in there....

Tom

From: Berger, Tom C.
Sent: Monday, March 23, 2020 6:22 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies – just want to make sure you are getting these emails. Understand if there are delays.

Tom

From: Berger, Tom C.
Sent: Thursday, March 19, 2020 5:22 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff – checking in again – thanks - Tom

From: Berger, Tom C.
Sent: Monday, March 16, 2020 1:40 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I know things are crazy but checking in again – thanks - Tom

From: Berger, Tom C.
Sent: Wednesday, March 11, 2020 3:43 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Checking in again - thanks

From: Berger, Tom C.
Sent: Friday, March 6, 2020 1:33 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

The submitter is quite anxious – can we touch base next week?

Thanks much - Tom

From: Berger, Tom C.
Sent: Tuesday, February 25, 2020 9:08 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just checking in on this – thanks - Tom

From: Berger, Tom C.
Sent: Thursday, February 20, 2020 12:18 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope that all is well.

Per our discussions, the submitter has modified the questions to focus on toxicity/risk issues and submitted them via CDX yesterday. Can we start looking at conference call dates the week of March 9?

Thanks and best regards,
Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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From: Berger, Tom C.
Sent: Wednesday, January 29, 2020 11:41 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies we keep playing phone tag – can we discuss how to convert the below questions into questions that would be acceptable to RAD so we can schedule a call with you and RAD? Your voicemail suggested the below are more legal/regulatory than risk-based questions. We still need the below questions answered – perhaps we tee up the more scientific ones for RAD then have the call to address both types of questions. The submitter is under growing commercial pressure.

Thanks much again - Tom

From: Berger, Tom C.
Sent: Monday, January 20, 2020 3:50 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies that we could not connect last week. Let's try to touch base tomorrow (Tuesday) if possible to discuss how to move this forward.

Thanks again – Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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From: Berger, Tom C.

Sent: Monday, January 13, 2020 2:50 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Importance: High

Hi Jeff –

Following is the list of questions we are considering submitting through CDX. Please let me know if these look ok.

Thanks again and best regards,
Tom

* * *

*(1) Based on review of the submitted physical-chemical properties test data, does EPA now agree that use **Ex. 4 CBI** as described in the PMN poses no unreasonable risk of injury and so plans to revoke the consent order?*

(2) If so, what is the process for revoking the current consent order? Does the submitter now need to request that EPA revoke the order, or will EPA itself initiate revocation? What is the expected timing for revocation? How would EPA communicate such revocation?

(3) How would revocation of the consent order impact the final SNUR for the subject substance?

(4) Would a SNUN be a more expedient approach?

* * *

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, January 8, 2020 8:56 AM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom, I am expecting information from the engineer today or tomorrow on the **Ex. 4 CBI** test, I left you a message. There is a new procedure for us to set up meeting with RAD. I am to have the submitter send in a list of questions for RAD, they will assign someone up there as a Lead person who has two weeks and will set a date for when we can have a meeting. This may be our best route to other than just me bugging them to get things done. There were a series of emails on this case last week but now everyone is back from the holidays I am trying to get this case moving again.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

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1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Tuesday, January 07, 2020 4:16 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope you had a great holiday! The client was wondering if we could have a conference call on this, this week or next. Please advise.

Thanks much – Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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Washington, D.C. | Brussels | San Francisco | Shanghai

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From: Berger, Tom C.
Sent: Tuesday, December 10, 2019 2:10 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just checking back in – thanks - Tom

From: Berger, Tom C.
Sent: Thursday, December 5, 2019 9:46 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

When we spoke before Thanksgiving (I hope you had a great one!) you indicated that the reports were being reviewed and that I should reach out to you in early December.

Is there any update?

Thanks much and best regards – Tom

Thomas C. Berger
Partner
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Washington, D.C. | Brussels | San Francisco | Shanghai

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From: Berger, Tom C.
Sent: Monday, November 18, 2019 1:17 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

The PMN submitter asked me to reach out to you to see if we can schedule a conference call (including EPA, K&H, and the submitter) on this case re status and pathforward.

Thanks - Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>

Sent: Friday, March 29, 2019 5:43 PM

To: Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Tom,

I set the meeting up for Wednesday April 3, at 11 am. RAD has accepted the invitation for that time.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Bauer, Jeff

Sent: Tuesday, March 26, 2019 11:37 AM

To: 'Berger, Tom C.' <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Tom, I left you a voice message, I am seeing what time it best for RAD to be part of the call.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Tuesday, March 26, 2019 11:30 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi folks –

Just thought I would check in with you on this.

Thanks again - Tom

From: Berger, Tom C.
Sent: Friday, March 22, 2019 2:12 PM
To: 'Bauer.jeff@Epa.gov' <Bauer.jeff@Epa.gov>; 'Schweer, Greg' <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: **Ex. 4 CBI**

Hi folks –

I hope you are doing well. Jeff – this is the PMN case that my colleague, Dr. Rhys Daniels, spoke with you about earlier this week.

The issue is development of data needed to amend the existing section 5(e) order for this substance to add an additional use, and EPA approval of protocols for same. Would the Agency be available for a short conference call on this on one of the following days?:

- March 27 (except 12-2 ET)
- April 2
- April 3
- April 4

This is becoming more urgent from a commercial standpoint.

Thanks much - Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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Message

From: Price, Amanda [price@khlaw.com]
Sent: 5/27/2020 3:30:45 PM
To: Cool, Rebecca [Cool.Rebecca@epa.gov]
CC: Sullivan, Andrew [sullivan.andrew@epa.gov]; Yan, James [Yan.James@epa.gov]; Schweer, Greg [Schweer.Greg@epa.gov]
Subject: RE: Subject: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19
Attachments: ATT00001.txt; Authorization Form for CBI transmittal by e-mail revised 4-8-2020-P-17-0195.pdf

Dear Becky,

Attached is the executed email authorization. We look forward to receiving the determination letter.

Best regards,

Amanda (Mandy) C. Price
Scientific Assistant
KELLER AND HECKMAN LLP
tel: +1 202.434.4236 | fax: +1 202.434.4646 | Price@khlaw.com
1001 G Street NW, Suite 500 West | Washington, DC 20001



From: Cool, Rebecca <Cool.Rebecca@epa.gov>
Sent: Wednesday, May 27, 2020 11:00 AM
To: Price, Amanda <price@khlaw.com>
Cc: Cool, Rebecca <Cool.Rebecca@epa.gov>; Sullivan, Andrew <sullivan.andrew@epa.gov>; Yan, James <Yan.James@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: Subject: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19

Company Contact: Amanda Price
COMPANY: Keller and Heckman

Dear Company Contact:

In an effort to encourage social distancing and help reduce community spread of COVID-19, most EPA staff have been authorized to telework until at least April 30, 2020. With a majority of EPA staff now teleworking from remote sites, some minor changes to the normal TSCA section 5 review processes, including the TSCA section 5(a)(3) determination processes, are required. Specifically, the normal process by which section 5(a)(3)(C) determination documents and section 5(e) orders are transmitted to submitters, because they contain information claimed as CBI, are hard copies submitted by the mail or courier services and via fax

machines. These methods of delivery are not available from remote sites and therefore other means of transmitting this information must be utilized.

Given this extraordinary situation, and to avoid delay in addressing TSCA section 5 requirements, the Agency is offering an option to allowed affected persons to agree to allow EPA to transmit these materials via normal non-encrypted Outlook email. If you agree to this, the Agency will transmit these documents to you via email during the period in which a majority of EPA staff is teleworking. In the absence of this agreement EPA may need to extend the review period for your submission or issue a unilateral order under Section 5(e). Please note that EPA is not requiring companies to agree to transmission via email. Rather this communication explains the constraints we are acting under, and the delays that would result in the absence of email transmission. Companies are free to choose as appropriate.

Also, please note that agreeing to this process is a limited waiver of the TSCA CBI procedural protections, which generally restricts the transmission of CBI over a non-encrypted email system. That said, EPA's email system is compliant with all applicable Federal government information security provisions, including the Federal Information Security Management Act, and EPA's email systems meet the level of protection required for storing and transmitting CBI. Furthermore, your agreement will not constitute a waiver of substantive CBI protections, meaning that the information transmitted and claimed as confidential will only be disclosed consistent with TSCA, other applicable laws, and associated implementing regulations.

If you wish to grant EPA a limited waiver to transmit the materials via EPA's email system during the period in which a majority of EPA staff is teleworking, please have your authorized representative complete, sign, and return the attached to Greg Schweer (Schweer.greg@epa.gov) as well as to any EPA staff who were cc'd on the email sent to you. If you have any questions about this communication or the described process, please contact Greg Schweer at (202) 564-8469 or the EPA Program Manager assigned to the case.

Becky Cool
New Chemicals Management Branch
Chemical Control Division
USEPA
cool.rebecca@epa.gov
202-564-9138

Agreement to authorize transmittal of TSCA Confidential Business Information (CBI) via Outlook email by designated Agency representatives during the period of EPA telework due to COVID-19

Documents concerning: PMN-17-0195

COMPANY authorizes EPA to transmit documents related to the above referenced TSCA submission, including information claimed as CBI, to **COMPANY** through EPA's Outlook email system. This authorization applies only during those periods where EPA staff working on PMN-XX-XXX are teleworking due to COVID-19 concerns and may be withdrawn at any time. Nothing in this authorization diminishes or otherwise limits **COMPANY'S** protections under TSCA to assert information as CBI, or otherwise authorizes the release of any information claimed as CBI without exhausting all provisions of TSCA protecting the release of such information. I have the authority to sign this on behalf of **COMPANY**



Signature of authorized person: _____

Name of authorized person printed or typed: Thomas C. Berger

Title: Partner

Email address: berger@khlaw.com

Telephone number Ex. 6 Personal Privacy (PP) _____

COMPANY _____ Keller and Heckman LLP _____

Message

From: Cool, Rebecca [Cool.Rebecca@epa.gov]
Sent: 5/27/2020 2:59:57 PM
To: price@khlaw.com
CC: Cool, Rebecca [Cool.Rebecca@epa.gov]; Sullivan, Andrew [sullivan.andrew@epa.gov]; Yan, James [Yan.James@epa.gov]; Schweer, Greg [Schweer.Greg@epa.gov]
Subject: Subject: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19
Attachments: Authorization Form for CBI transmittal by e-mail revised 4-8.docx

Company Contact: Amanda Price
COMPANY: Keller and Heckman

Dear Company Contact:

In an effort to encourage social distancing and help reduce community spread of COVID-19, most EPA staff have been authorized to telework until at least April 30, 2020. With a majority of EPA staff now teleworking from remote sites, some minor changes to the normal TSCA section 5 review processes, including the TSCA section 5(a)(3) determination processes, are required. Specifically, the normal process by which section 5(a)(3)(C) determination documents and section 5(e) orders are transmitted to submitters, because they contain information claimed as CBI, are hard copies submitted by the mail or courier services and via fax machines. These methods of delivery are not available from remote sites and therefore other means of transmitting this information must be utilized.

Given this extraordinary situation, and to avoid delay in addressing TSCA section 5 requirements, the Agency is offering an option to allowed affected persons to agree to allow EPA to transmit these materials via normal non-encrypted Outlook email. If you agree to this, the Agency will transmit these documents to you via email during the period in which a majority of EPA staff is teleworking. In the absence of this agreement EPA may need to extend the review period for your submission or issue a unilateral order under Section 5(e). Please note that EPA is not requiring companies to agree to transmission via email. Rather this communication explains the constraints we are acting under, and the delays that would result in the absence of email transmission. Companies are free to choose as appropriate.

Also, please note that agreeing to this process is a limited waiver of the TSCA CBI procedural protections, which generally restricts the transmission of CBI over a non-encrypted email system. That said, EPA's email system is compliant with all applicable Federal government information security provisions, including the Federal Information Security Management Act, and EPA's email systems meet the level of protection required for storing and transmitting CBI. Furthermore, your agreement will not constitute a waiver of substantive CBI protections, meaning that the information transmitted and claimed as confidential will only be disclosed consistent with TSCA, other applicable laws, and associated implementing regulations.

If you wish to grant EPA a limited waiver to transmit the materials via EPA's email system during the period in which a majority of EPA staff is teleworking, please have your authorized representative complete, sign, and return the attached to Greg Schweer (Schweer.greg@epa.gov) as well as to any EPA staff who were cc'd on the email sent to you. If you have any questions about this communication or the described process, please contact Greg Schweer at (202) 564-8469 or the EPA Program Manager assigned to the case.

Becky Cool

New Chemicals Management Branch
Chemical Control Division
USEPA
cool.rebecca@epa.gov
202-564-9138

Agreement to authorize transmittal of TSCA Confidential Business Information (CBI) via Outlook email by designated Agency representatives during the period of EPA telework due to COVID-19

Documents concerning: PMN-17-0195

COMPANY authorizes EPA to transmit documents related to the above referenced TSCA submission, including information claimed as CBI, to **COMPANY** through EPA's Outlook email system. This authorization applies only during those periods where EPA staff working on PMN-XX-XXX are teleworking due to COVID-19 concerns and may be withdrawn at any time. Nothing in this authorization diminishes or otherwise limits **COMPANY'S** protections under TSCA to assert information as CBI, or otherwise authorizes the release of any information claimed as CBI without exhausting all provisions of TSCA protecting the release of such information. I have the authority to sign this on behalf of **COMPANY**

Signature of authorized person: _____

Name of authorized person printed or typed: _____

Title: _____

Email address: _____

Telephone number: _____

COMPANY _____

Message

From: Berger, Tom C. [Berger@khlaw.com]
Sent: 5/20/2020 12:51:42 PM
To: Bauer, Jeff [Bauer.Jeff@epa.gov]
CC: Price, Amanda [price@khlaw.com]; Schweer, Greg [Schweer.Greg@epa.gov]; Daniels, Rhys G. [daniels@khlaw.com]
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I will send another MS Outlook invite with dial-in instructions for next Wednesday, May 27th at 2 p.m. You can forward that to RAD, etc.

Thanks again - Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, May 13, 2020 1:32 PM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom,

I sent a meeting request to you three for May 27th at 2 p.m. to give a status update as requested.

Thanks

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Wednesday, May 13, 2020 12:53 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just seeing if it makes sense to set up a conference call in a week or two.

Thanks much again - Tom

From: Berger, Tom C.
Sent: Friday, May 8, 2020 11:14 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Jeff/Greg – thanks again.

Can/should we schedule a conference call with the submitter in a week or two?

Happy Friday!

Tom

From: Berger, Tom C.
Sent: Thursday, May 7, 2020 4:17 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: Re: **Ex. 4 CBI**

Jeff - thanks much.

Tom

On May 7, 2020, at 4:03 PM, Bauer, Jeff <Bauer.Jeff@epa.gov> wrote:

Tom, I hope you hanging in there as well, I have an email out to see if I can get a status update on the Assessor and to address your questions sent into CDX for a meeting.

Jeff

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

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1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Thursday, May 07, 2020 1:57 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff – Just touching base as the submitter has requested a status update.

Thanks again - Tom

From: Berger, Tom C.
Sent: Tuesday, May 5, 2020 11:56 AM
To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; 'Schweer, Greg' <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff – Just checking in on this – thanks - Tom

From: Berger, Tom C.
Sent: Wednesday, April 29, 2020 11:12 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I just thought I would check in on this and see if the Agency needs any additional information.

Thanks again and best regards,
Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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From: Berger, Tom C.
Sent: Thursday, April 23, 2020 7:13 PM
To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Jeff - thanks much.

Your recent voicemail and follow-up email indicated that the EPA Chemist has evaluated the study" on **Ex. 4 CBI** but that the reviewer did have a few questions and comments:

Ex. 4 CBI

Ex. 4 CBI

To specifically answer the Chemist's questions:

Ex. 4 CBI

Ex. 4 CBI

* * *

We trust that you find this information useful in resolved all outstanding issues. As always, if you have any questions please do not hesitate to contact us.

Best regards,
Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Tuesday, April 21, 2020 5:17 PM
To: Daniels, Rhys G. <daniels@khlaw.com>; Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: **Ex. 4 CBI**

I am moving forward with the review based on the information I have on the two studies, I wanted to share with you her comments on the test. **Ex. 4 CBI**

Ex. 4 CBI RAD has the
information and I am trying to get them to do the risk assessment based on **Ex. 4 CBI**

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Daniels, Rhys G. <daniels@khlaw.com>
Sent: Tuesday, April 21, 2020 4:58 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: **Ex. 4 CBI**

Jeff,

As always, we hope that all is well.

Per your recent voicemail and follow-up email concerning the **Ex. 4 CBI** case, we understand that the chemist has two questions concerning **Ex. 4 CBI**

Ex. 4 CBI

Thanks in advance for your response.

Rhys G. Daniels, Ph.D.
Staff Scientist
tel: +1 202.434.4270 | fax: +1 202.434.4646 | daniels@khlaw.com
1001 G Street NW, Suite 500 West | Washington, DC 20001

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Thursday, April 16, 2020 1:02 PM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: **Ex. 4 CBI**

Tom,

The chemist sent me a memo **Ex. 4 CBI** and they had two questions, I called and left you a message today **Ex. 4 CBI** I sent RAD a request last week to update the HH assessment **Ex. 4 CBI** as in my April 4, 2020 email to you. I have two emails into RAD on this case and will try an update you again in a week or so. I requested RAD set up a date with me to have a meeting to discuss how to proceed with this PMN.

Thanks
Jeff

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M

1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Thursday, April 16, 2020 12:28 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope that all is well.

Just checking in re status update. A non-CBI-containing email from you would probably be the best (if needed at some later time we can use EPA's new CBI via email authorization form if the submitter agrees).

Thanks again – Tom

From: Berger, Tom C.
Sent: Wednesday, April 8, 2020 11:06 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Jeff – thanks much for the update. Hope you and all at EPA are staying safe.

Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, April 8, 2020 11:03 AM
To: Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom,

Ex. 4 CBI

I will follow up with you next wed with a status update.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Wednesday, April 08, 2020 10:48 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Greg –

I was just going through my to-do list and thought I would circle back on these two cases. I hope everyone is hanging in there.

Thanks again – Tom

From: Berger, Tom C.
Sent: Monday, March 30, 2020 3:46 PM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Greg / all – completely understood – thank you so much.

Tom

From: Schweer, Greg <Schweer.Greg@epa.gov>
Sent: Monday, March 30, 2020 3:42 PM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>
Subject: RE: **Ex. 4 CBI**

Hi Tom.

I am not ignoring you. I did check with Jeff Bauer early last week on this case. He filled me in on the requests he had made of RAD to review submitted test data and your request for a meeting. However, believe it or not, we have been having issues reliably being able to access our CBI-secure LAN. This hampers our ability to efficiently complete work. I will check on the status of your case as soon as I can.

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Monday, March 30, 2020 11:51 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Greg –

Hope all is well.

Just thought I would check in with you on the **Ex. 4 CBI** LVEA (Lauren Davis) and **Ex. 4 CBI** with Jeff Bauer.

Thanks all always - Tom

From: Berger, Tom C.
Sent: Tuesday, March 24, 2020 11:12 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Greg – thanks so much as always. I also have an LVE with Lauren Davis **Ex. 4 CBI** held up in the process. Lauren has been responsive but the case has stalled (again, however, I understand the challenges you are facing).

These are my two “priority” cases.

Tom

From: Schweer, Greg <Schweer.Greg@epa.gov>
Sent: Tuesday, March 24, 2020 11:07 AM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: Re: **Ex. 4 CBI**

Tom,

Yes, things are a bit crazy. I will check into the case status today or tomorrow.

Sent from my iPhone

On Mar 24, 2020, at 10:48 AM, Berger, Tom C. <Berger@khlaw.com> wrote:

Hi Greg –

Obviously things are crazy and I don't want to push Jeff too hard but no response from Jeff on this case for a month.

Hang in there....

Tom

From: Berger, Tom C.
Sent: Monday, March 23, 2020 6:22 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies – just want to make sure you are getting these emails. Understand if there are delays.

Tom

From: Berger, Tom C.
Sent: Thursday, March 19, 2020 5:22 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff – checking in again – thanks - Tom

From: Berger, Tom C.
Sent: Monday, March 16, 2020 1:40 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I know things are crazy but checking in again – thanks - Tom

From: Berger, Tom C.
Sent: Wednesday, March 11, 2020 3:43 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Checking in again - thanks

From: Berger, Tom C.
Sent: Friday, March 6, 2020 1:33 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

The submitter is quite anxious – can we touch base next week?

Thanks much - Tom

From: Berger, Tom C.
Sent: Tuesday, February 25, 2020 9:08 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just checking in on this – thanks - Tom

From: Berger, Tom C.
Sent: Thursday, February 20, 2020 12:18 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope that all is well.

Per our discussions, the submitter has modified the questions to focus on toxicity/risk issues and submitted them via CDX yesterday. Can we start looking at conference call dates the week of March 9?

Thanks and best regards,
Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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From: Berger, Tom C.
Sent: Wednesday, January 29, 2020 11:41 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies we keep playing phone tag – can we discuss how to convert the below questions into questions that would be acceptable to RAD so we can schedule a call with you and RAD? Your voicemail suggested the below are more legal/regulatory than risk-based questions. We still need the below questions answered – perhaps we tee up the more scientific ones for RAD then have the call to address both types of questions. The submitter is under growing commercial pressure.

Thanks much again - Tom

From: Berger, Tom C.
Sent: Monday, January 20, 2020 3:50 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies that we could not connect last week. Let's try to touch base tomorrow (Tuesday) if possible to discuss how to move this forward.

Thanks again – Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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From: Berger, Tom C.
Sent: Monday, January 13, 2020 2:50 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**
Importance: High

Hi Jeff –

Following is the list of questions we are considering submitting through CDX. Please let me know if these look ok.

Thanks again and best regards,
Tom

* * *

*(1) Based on review of the submitted physical-chemical properties test data, does EPA now agree that use **Ex. 4 CBI** as described in the PMN poses no unreasonable risk of injury and so plans to revoke the consent order?*

(2) If so, what is the process for revoking the current consent

order? Does the submitter now need to request that EPA revoke the order, or will EPA itself initiate revocation? What is the expected timing for revocation? How would EPA communicate such revocation?

(3) How would revocation of the consent order impact the final SNUR for the subject substance?

(4) Would a SNUN be a more expedient approach?

* * *

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, January 8, 2020 8:56 AM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom, I am expecting information from the engineer today or tomorrow on the **Ex. 4 CBI** test, I left you a message. There is a new procedure for us to set up meeting with RAD. I am to have the submitter send in a list of questions for RAD, they will assign someone up there as a Lead person who has two weeks and will set a date for when we can have a meeting. This may be our best route to other than just me bugging them to get things done. There were a series of emails on this case last week but now everyone is back from the holidays I am trying to get this case moving again.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Tuesday, January 07, 2020 4:16 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope you had a great holiday! The client was wondering if we could have a conference call on this, this week or next. Please advise.

Thanks much – Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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From: Berger, Tom C.
Sent: Tuesday, December 10, 2019 2:10 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just checking back in – thanks - Tom

From: Berger, Tom C.
Sent: Thursday, December 5, 2019 9:46 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

When we spoke before Thanksgiving (I hope you had a great one!) you indicated that the reports were being reviewed and that I should reach out to you in early December.

Is there any update?

Thanks much and best regards – Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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From: Berger, Tom C.
Sent: Monday, November 18, 2019 1:17 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

The PMN submitter asked me to reach out to you to see if we can schedule a conference call (including EPA, K&H, and the submitter) on this case re status and pathforward.

Thanks - Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Friday, March 29, 2019 5:43 PM
To: Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom,
I set the meeting up for Wednesday April 3, at 11 am. RAD has accepted the invitation for that time.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Bauer, Jeff
Sent: Tuesday, March 26, 2019 11:37 AM
To: 'Berger, Tom C.' <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom, I left you a voice message, I am seeing what time it best for RAD to be part of the call.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M

1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Tuesday, March 26, 2019 11:30 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi folks –

Just thought I would check in with you on this.

Thanks again - Tom

From: Berger, Tom C.
Sent: Friday, March 22, 2019 2:12 PM
To: 'Bauer.jeff@Epa.gov' <Bauer.jeff@Epa.gov>; 'Schweer, Greg' <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: **Ex. 4 CBI**

Hi folks –

I hope you are doing well. Jeff – this is the PMN case that my colleague, Dr. Rhys Daniels, spoke with you about earlier this week.

The issue is development of data needed to amend the existing section 5(e) order for this substance to add an additional use, and EPA approval of protocols for same. Would the Agency be available for a short conference call on this on one of the following days?:

- March 27 (except 12-2 ET)
- April 2
- April 3
- April 4

This is becoming more urgent from a commercial standpoint.

Thanks much - Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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Message

From: Willard, Travis L [tlwill@ascendmaterials.com]
Sent: 5/14/2020 7:21:59 PM
To: Hoffer, Danielle [hoffer.danielle@epa.gov]
CC: Scott J. Burya, Ph.D. [sburya@lawbc.com]; Schweer, Greg [Schweer.Greg@epa.gov]
Subject: RE: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19

Danielle, thanks for the message. I have forwarded it to our legal team for review.

Regards,

Travis

From: Hoffer, Danielle <hoffer.danielle@epa.gov>
Sent: Thursday, May 14, 2020 1:17 PM
To: Willard, Travis L <tlwill@ascendmaterials.com>
Cc: Scott J. Burya, Ph.D. <sburya@lawbc.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: [EXTERNAL] Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19

CAUTION: This email originated from outside of the organization. Do not click links or open attachments unless you recognize the sender and know the content is safe.

Dear Travis Willard,

Scott requested that I send this authorization form for transmitting CBI over email to you so I can send some of the draft reports for your cases (P-20-0078, P-20-0080-82). Below are more details about why we are requesting this:

In an effort to encourage social distancing and help reduce community spread of COVID-19, most EPA staff have been authorized to telework. With a majority of EPA staff now teleworking from remote sites, some minor changes to the normal TSCA section 5 review processes, including the TSCA section 5(a)(3) determination processes, are required. Specifically, the normal process by which section 5(a)(3)(C) determination documents, section 5(e) orders, and assessment reports are transmitted to submitters, because they contain information claimed as CBI, are hard copies submitted by the mail or courier services and via fax machines. These methods of delivery are not available from remote sites and therefore other means of transmitting this information must be utilized.



Given this extraordinary situation, and to avoid delay in addressing TSCA section 5 requirements, the Agency is offering an option to allowed affected persons to agree to allow EPA to transmit these materials via normal non-encrypted Outlook email. If you agree to this, the Agency will transmit these documents to you via email during the period in which a majority of EPA staff is teleworking. In the absence of this agreement EPA may need to extend the review period for your submission or issue a unilateral order under Section 5(e). Please note that EPA is not requiring companies to agree to transmission via email. Rather this communication explains the constraints we are acting under, and the delays that would result in the absence of email transmission. Companies are free to choose as appropriate.

Also, please note that agreeing to this process is a limited waiver of the TSCA CBI procedural protections, which generally restricts the transmission of CBI over a non-encrypted email system. That said, EPA's email system is compliant with all applicable Federal government information security provisions, including the Federal Information Security Management Act, and EPA's email systems meet the level of protection required for storing and transmitting CBI. Furthermore, your agreement will not constitute a waiver of substantive CBI protections, meaning that the information transmitted and claimed as confidential will only be disclosed consistent with TSCA, other applicable laws, and associated implementing regulations.

If you wish to grant EPA a limited waiver to transmit the materials via EPA's email system during the period in which a majority of EPA staff is teleworking, please have your authorized representative complete (e.g., add the case numbers[all four]), sign, and return the attached to Greg Schweer (Schweer.greg@epa.gov) as well as to any EPA staff who were cc'd on the email sent to you. If you have any questions about this communication or the described process, please contact Greg Schweer at (202) 564-8469 or the EPA Program Manager assigned to the case.

Best Regards,

Danielle Hoffer
Environmental Protection Specialist
U.S. Environmental Protection Agency
Office of Chemical Safety and Pollution Prevention
Office of Pollution Prevention and Toxics
Chemical Control Division
New Chemicals Management Branch
(202) 564-0556

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Appointment

From: Scott, Elizabeth [Scott.Elizabeth@epa.gov]
Sent: 4/8/2019 12:47:21 PM
To: Moss, Kenneth [Moss.Kenneth@epa.gov]; Schmit, Ryan [schmit.ryan@epa.gov]; Pierce, Alison [Pierce.Alison@epa.gov]; Franz, Christina [Christina_Franz@americanchemistry.com]
CC: Schweer, Greg [Schweer.Greg@epa.gov]; Sahar_Osman-Sypher@americanchemistry.com; Vendinello, Lynn [Vendinello.Lynn@epa.gov]; Mark Duvall [MDuvall@bdlaw.com]; Lisa Marie Nespoli [lisamarie.nespoli@covestro.com]; Mark Joseph McKinney [mark.mckinney@basf.com]; Marcia Levinson [marcia.levinson@covestro.com]; Stedeford, Todd [Stedeford.Todd@epa.gov]; Adam Kuhl [adam_kuhl@huntsman.com]; Wormell, Lance [Wormell.Lance@epa.gov]
Subject: Meeting with ACC
Attachments: ACC letter to EPA re April 10 meeting on isocyanates - 4-5-19.pdf; ACC_EPA Meeting Agenda on Isocyanates-Based SNURs 2019 04 10.pdf
Location: DCRoomEast3371A/DC-EPA-EAST-OCSPP-OPPT

Start: 4/10/2019 12:00:00 PM
End: 4/10/2019 1:00:00 PM
Show Time As: Tentative

Teleconference Line:

Ex. 6 Personal Privacy (PP)

Conference ID: Ex. 6 Personal Privacy (PP)

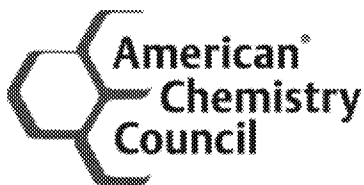
LEADER: Tala

Meeting Location:

Environmental Protection Agency
William Jefferson Clinton East Building
1201 Constitution Avenue NW
Conference Room: 3371A (3rd Floor)
Washington, DC 20460

Please bring photo identification and once through security, please have them call (202) 564-3810 for an escort to meeting location.

Please provide list of names of five or more attendees coming from your group – this will speed up clearing security check-in.



April 5, 2019

By email to henry.tala@epa.gov

Dr. Tala Henry (74013T)
Acting Deputy Director for Programs
Office of Pollution Prevention and Toxics
Office of Chemical Safety and Pollution Prevention
Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Re: EPA's Approach to Isocyanate-Based Polymers Under TSCA Section 5

Dear Dr. Henry:

On behalf of the American Chemistry Council and its Diisocyanates and Aliphatic Diisocyanates Panels (collectively ACC), thank you for scheduling a meeting with us on April 10 at 8:00 a.m. This letter presents the questions ACC would like to discuss at the meeting.

The purpose of the meeting is to help ACC better understand EPA's approach to isocyanate-based polymers under section 5 of TSCA. The outcome of the meeting could help ACC and its members, and the customers of those members, develop polymers with improved risk profiles, and also help expedite the SNUR rulemaking process.

As a preliminary matter, we point out that EPA published an Action Plan for methylene diphenyl diisocyanate (MDI) and related compounds in April 2011. Since then, it has issued final or proposed SNURs for at least 58 isocyanate-based polymers and prepolymers. Of those 58 SNURs, EPA has finalized 28. A total of 30 SNURs, more than half, remain under review. EPA last finalized a SNUR for an isocyanate-based polymer in December 2014, over four years ago. See Attachment 1 for details.

ACC has submitted comments on almost all of the 30 proposed SNURs raising concerns that – to date – EPA has not answered. We hope that the meeting will address those concerns.

1. When will EPA update the Chemical Categories description for diisocyanates?

ACC would like to know when EPA will update at least the Chemical Categories description on diisocyanates. EPA has told ACC that it no longer follows the guidance in that description. ACC members and their customers rely on EPA guidance as to what limits are acceptable, so an updated description is critical to ensuring our members have clear guidance regarding the parameters EPA considers when issuing these SNURs.

2. Why does EPA propose maximum percentages for residual isocyanates in some section 5(e) orders and SNURs for isocyanate-based polymers, and not in others, and use differing percentages when it does propose these limitations?

In several recent SNURs for isocyanate-based polymers, EPA has proposed a ceiling on residual isocyanate content. ACC would also like to understand what EPA means by “residual isocyanate.” Does this refer only to unreacted monomer? It is important for EPA to clarify this term, because EPA does not have authority under section 5 to regulate the monomer itself as it is used as a reactant (an existing use), and the monomer is not part of the polymer or pre-polymer that is the PMN substance.

The proposed SNURs with a ceiling include those in the following PMN substances:

- P-18-51: “It is a significant new use to import the substance with greater than 0.1% isocyanate content.”
- P-17-374: “It is a significant new use to import the substance with more than 0.1% residual isocyanate.”
- P-17-361: “It is a significant new use to manufacture the substance containing greater than 0.25% residual isocyanate”
- P-17-304: “It is a significant new use to manufacture (includes importing) the substance to contain more than 0.1% residual isocyanate by weight.”
- P-17-222: “It is a significant new use to import the chemical substance containing greater than 0.15 percent residual isocyanate.”
- P-17-170: “It is a significant new use to manufacture the chemical substance containing greater than 0.1 percent residual isocyanate”
- P-17-10: “It is a significant new use to manufacture the chemical substance ... containing greater than 0.1% residual isocyanate.”
- P-16-493: “It is a significant new use to import the PMN substance to contain more than 0.1% residual isocyanate by weight.”
- P-16-363: “It is a significant new use to manufacture, process, or use the substance with a residual of free isocyanate monomers greater than 0.1 percent by weight.”
- P-16-99: “It is a significant new use to manufacture the chemical substance containing greater than 0.2% residual isocyanate.”
- P-15-707: “A significant new use is any manufacture, processing, or use of the PMN substance with more than [0.1]% residual isocyanate by weight.”¹

¹ The proposed regulatory text refers to “1%”, but the preamble refers to “0.1%”. ACC assumes that EPA meant to refer to “0.1%” in the regulatory text.

- P-15-706: “A significant new use is any manufacture, processing, or use of the PMN substance with more than 0.1% residual isocyanate by weight.”

Thus, EPA has proposed a maximum percentage limitation in 12 of the 58 SNURs for isocyanate-based polymers since April 2011. It proposed a 0.1% limit (variously phrased) for 10 of them. The other percentages were 0.15%, 0.2%, and 0.25%.

ACC would like to understand why EPA proposed a maximum percentage limitation in some section 5(e) orders and SNURs for isocyanate-based polymers and not in others, and why it selected 0.1% in most cases, but proposed higher percentages in three instances.

3. Why does EPA propose limits on average molecular weight in some section 5(e) orders and SNURs for isocyanate-based polymers, and not in others, and use differing molecular weight limits when it does propose them?

In several recent SNURs for isocyanate-based polymers, EPA has proposed a ceiling on low-molecular weight species. They include proposed SNURs for the following PMN substances:

- P-18-40: “It is a significant new use to import the substance if the number average molecular weight is less than or equal to 1000 daltons.”
- P-17-374: “It is a significant new use to import the substance at a number average molecular weight less than 1000 daltons.”
- P-17-361: “It is a significant new use to manufacture the substance ... [with] an average molecular weight less than 2,280 daltons.”
- P-17-170: “It is a significant new use to manufacture the chemical substance ... [with] an average molecular weight below 1,000 daltons.”
- P-17-10: “It is a significant new use to manufacture the chemical substance with an average molecular weight below 2,000 daltons”
- P-15-559: “A significant new use of the substance is manufacture of the substance where the average molecular weight is below 7,500 daltons, and where any molecular weight species is below 1,000 daltons.”
- P-15-278: “The significant new use is manufacture of the substance where the average molecular weight is below 2,500 daltons and where any molecular weight species is below 1,000 daltons.”
- P-12-326: “The significant new uses are: (i) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(j) (manufacture, processing, or use where the molecular weight is 1000 daltons or more).”² [Note: presumably should be 1000 daltons or less.]

Thus, EPA proposed a minimum molecular weight in 8 of the 58 SNURs since April 2011. The minimums proposed have included 1,000 daltons, 2,000 daltons, 2,500 daltons, and 2,280 daltons. In addition, EPA has expressed concerns about average molecular weights below 7,500 daltons.

² The text should probably refer to “1000 daltons or less,” not “1000 daltons or more.” The preamble refers to “1000 daltons or less.”

Some of these proposed minimums and the statement of concern are inconsistent with the 2010 Chemical Categories section on diisocyanates. It states:

Structures with an isocyanate equivalent weight of $\geq 5,000$ are presumed not to pose a hazard under any condition. Typically, concerns are confined to those species with molecular weights $< 1,000$.

ACC would like to understand why EPA proposed a minimum average molecular weight in some section 5(e) orders and SNURs for isocyanate-based polymers and not others, and why it selected 1,000 daltons in most cases, but proposed higher molecular weights in three cases.

4. How Did EPA Calculate the NCEL of 0.9 mg/m³?

For 3 of the 58 SNURs for isocyanate-based polymers since April 2011, EPA has proposed a New Chemical Exposure Limit (NCEL) of 0.9 mg/m³. They are the proposed SNURs for P-16-99, P-15-707, and P-15-706.

The SNUR for P-04-834 set a NCEL of 0.05 mg/m³ TWA₈. In addition, the section 5(e) order for P-16-493 cautioned:

Inhalation exposure should be limited to < 0.05 mg/m³ as an 8-hours time-weighted average (TWA) for combined polyisocyanates and diisocyanates.

ACC would like to understand the basis for these NCELs and how EPA calculated the 0.9 mg/m³ NCEL and the 0.05 mg/m³ NCEL.

5. Which health effects does EPA associate with isocyanates?

As indicated in the attached table, EPA has described its expected health effects from isocyanate-based polymers in widely varying terms. It mentioned dermal and respiratory sensitization consistently. In some section 5(e) orders and SNURs, however, EPA has asserted concerns for oncogenicity, mutagenicity, neurotoxicity, developmental toxicity, and lung toxicity based on cationic binding. Most, however, have not referred to those health effects.

ACC would like to understand which health effects of isocyanates are of concern to EPA; why it cites some health effects for some substances and not others; and whether the isocyanate-based concerns vary from substance to substance and, if so, what the basis is for EPA's selection of particular health effects for a given SNUR.

6. Has EPA reviewed the basis for its assertion that isocyanates are the leading cause of occupational asthma, with an incidence rate as high as 20%?

The section 5(f) order for P-17-24 and P-17-25 declared:

Isocyanate exposure has been identified as the leading attributable cause of work-related asthma, and prevalence in the exposed workforce has been estimated at 1-20 percent (see Refs. 1 and 2).

This statement is taken verbatim from the proposed SNUR for toluene diisocyanates and related compounds, 80 Fed. Reg. 2068, 2070 (Jan. 15, 2015). Numerous section 5(e) orders do not make this statement explicitly, but instead they refer to the 2006 NIOSH Alert, “Preventing Asthma and Death from MDI Exposure During Spray-on Truck Bed Liner and Related Applications,” which states:

Isocyanates are the leading attributable chemical cause of occupational asthma in the United States and many other industrialized countries [Tarlo et al. 1997b].

ACC has reviewed the sources cited by EPA and NIOSH for this assertion and found them to be outdated and inaccurate. See Attachment 2.

ACC encourages EPA to review the more recent scientific literature, which does not support the assertion that diisocyanates are the leading cause of occupational asthma. Recent data show a consistent picture of a decline in asthma rates associated with diisocyanates over the last decade, even as production rates of diisocyanates have increased. The reduction in diisocyanate-related occupational asthma is primarily due to a variety of product stewardship activities, including education and training, enhanced worker awareness, improved work practices, use of less volatile diisocyanate forms (e.g., pre-polymers), improved engineering controls (e.g., containment and/or ventilation), better medical surveillance programs, minimization of peak exposures, and continuing emphasis on compliance with existing exposure standards. These product stewardship efforts are key to further reductions in cases.

According to the NIOSH Work-Related Lung Disease Surveillance System (eWoRLD), in the four U.S. states surveyed (California, Massachusetts, Michigan, and New York) the most recent work-related asthma statistics from 2009-2012 indicate that diisocyanates are not in the top ten “frequently reported agent categories associated with work-related asthma,” falling to number 19 (1.0% of work-related asthma cases).

7. Why is EPA not finalizing SNURs for isocyanate-based polymers?

EPA currently has 30 proposed SNURs for isocyanate-based polymers pending review. It has not finalized a proposed SNUR or a direct final SNUR for an isocyanate-based polymer since December 2014, over four years ago.

Any manufacturers and processors of these polymers, other than the PMN submitters, should be subject to the same restrictions as those to which the PMN submitters are subject.

ACC would like to understand why EPA continues to issue direct final SNURs and/or proposed SNURs for isocyanate-based polymers, but does not finalize them. ACC also requests a response to the comments it has submitted on many of the pending SNURs.

8. What is the significance of the medical surveillance requirement in a recent section 5(e) order and proposed SNUR?

For the first time that ACC is aware, EPA has included a medical surveillance requirement in a section 5(e) order and proposed SNUR. The proposed SNUR for P-17-231 states:

It is a significant new use to manufacture the substance without conducting medical surveillance as specified in the Order.

It is not clear whether the medical surveillance requirement was prompted by EPA concerns for isocyanates or for other moieties in that polymer.

ACC would like to understand why EPA included a medical surveillance requirement in that section 5(e) order and proposed SNUR (and, in particular, whether it was prompted by a concern about isocyanates). ACC would also like to know whether EPA intends to require medical surveillance in future section 5(e) orders and SNURs for isocyanate-based polymers, and, if so, what the basis is for this requirement and the intended scope of that medical surveillance.

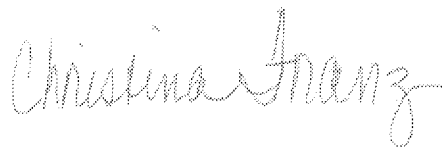
Moving forward, ACC would very much like to partner with EPA to resolve the issues outlined above. ACC is available to educate Agency staff on our chemistries to help expedite chemical reviews and address EPA's concerns. In addition, we would like to work with EPA scientists to design test plans to develop toxicological data to fulfill apparent data gaps, particularly for isocyanate prepolymers.

We look forward to the opportunity to discuss these suggestions with your staff at the April 10 meeting. In the meantime, if you have questions or comments, please contact Christina Franz at (202) 249-6406 and christina_franz@americanchemistry.com, or Sahar Osman-Sypher at (202) 249-6721 and sahar_osman-sypher@americanchemistry.com.

Sincerely,



Sahar Osman-Sypher
Director, Diisocyanates and Aliphatic
Diisocyanates Panels



Christina Franz
Senior Director, Regulatory & Technical
Affairs

Attachments

cc: Alexandra Dunn
Dr. Jeffery Morris

Attachment 1

SNURs for Isocyanate-Based Polymers Since April 2011

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-18-51	Proposed 40 C.F.R. § 721.11242 84 Fed. Reg. 9999 (Mar. 19, 2019) (proposed SNUR)	Comment period closes May 3, 2019.	§ 5(e) order: None specifically identified as attributable to isocyanates.	No	“It is a significant new use to import the substance with greater than 0.1% isocyanate content.”
P-18-40	Proposed 40 C.F.R. § 721.11239 84 Fed. Reg. 9999 (Mar. 19, 2019) (proposed SNUR)	Comment period closes May 3, 2019.	§ 5(e) order: None specifically identified as attributable to isocyanates.	No	“It is a significant new use to import the substance if the number average molecular weight is less than or equal to 1000 daltons.”

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-17-374	Proposed 40 C.F.R. § 721.11239 84 Fed. Reg. 9999 (Mar. 19, 2019) (proposed SNUR)	Comment period closes May 3, 2019.	§ 5(e) order unavailable. None specifically identified in SNUR preamble as attributable to isocyanates.	No	“It is a significant new use to import the substance with more than 0.1% residual isocyanate. It is a significant new use to import the substance at a number average molecular weight less than 1000 daltons.”
P-17-361	Proposed 40 C.F.R. § 721.11211 83 Fed. Reg. 57634 (Nov. 15, 2018) (proposed SNUR)	Under EPA review. Comment period closed Dec. 31, 2018.	§ 5(e) order: “The concern for eye and skin irritation, and sensitization (dermal and respiratory) is based primarily on the isocyanate moiety.”	No	“It is a significant new use to manufacture the substance containing greater than 0.25% residual isocyanate or an average molecular weight less than 2,280 daltons.”

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-17-304	Proposed 40 C.F.R. § 721.11206 83 Fed. Reg. 57634 (Nov. 15, 2018) (proposed SNUR)	Under EPA review. Comment period closed Dec. 12, 2018.	§ 5(e) order: “Toxicological Endpoints of Concern: There is concern for sensitization EPA's estimate of the human health hazard of the PMN substance is based on its estimated physical/chemical properties and other structural information, including the presence of Low Molecular Weight (LMW) moieties in the polymer.”	No	“It is a significant new use to manufacture (includes importing) the substance to contain more than 0.1% residual isocyanate by weight.”
P-17-231	Proposed 40 C.F.R. § 721.11112 83 Fed. Reg. 43538 (Aug. 27, 2018) (direct final SNUR); 83 Fed. Reg. 43607 (Aug. 27, 2019) (proposed SNUR)	Direct final SNUR withdrawn Oct. 24, 2018. Proposed SNUR under review.	§ 5(e) order: “No significant health concerns for the PMN substance as it is now. If made differently (different ratio of monomers), there may be isocyanate moieties present that would be of concern for human health endpoints of dermal sensitization, respiratory sensitization, lung effects, neurotoxicity and developmental toxicity. Basis: Diisocyanate Chemicals Category NIOSH Alert on Preventing Asthma and Death from MDI Exposure During Spray-on Truck Bed Liner and Related Applications As the PMN substance is currently described, there is no risk to workers, but if the substance is made with a different percent residual of isocyanate, there may be unreasonable risk to workers.”	No	“It is a significant new use to manufacture the substance without conducting medical surveillance as specified in the Order.”

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-17-222	Proposed 40 C.F.R. § 721.11111 83 Fed. Reg. 43538 (Aug. 27, 2018) (direct final SNUR); 83 Fed. Reg. 43607 (Aug. 27, 2019) (proposed SNUR)	Direct final SNUR withdrawn Oct. 24, 2018. Proposed SNUR under review.	§ 5(e) order: “There are concerns for dermal sensitization, respiratory sensitization, lung effects, neurotoxicity and developmental toxicity. Basis: Diisocyanate Chemicals Category NIOSH Alert on Preventing Asthma and Death from MDI Exposure During Spray-on Truck Bed Liner and Related Applications As manufactured, there are no risks to workers for exposure of the PMN. Due to the possibility of isocyanate residuals if it is made different, there is concern for sensitization. Exposure to diisocyanate may cause the following effects: skin irritation and allergic reaction, respiratory irritation, respiratory sensitization, and lung toxicity; some diisocyanates also may cause cancer. It is especially important to note that contact with the skin may lead to respiratory sensitization or cause other allergic reactions. Workers should take precaution to avoid breathing vapors, mists or aerosols. Inhalation exposure should be limited to <0.05 mg/m ³ as an 8-hours time-weighted average (TWA) for combined polyisocyanates and diisocyanates.”	No	“It is a significant new use to import the chemical substance containing greater than 0.15 percent residual isocyanate.”

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-17-170	Proposed 40 C.F.R. § 721.11107 83 Fed. Reg. 43538 (Aug. 27, 2018) (direct final SNUR); 83 Fed. Reg. 43607 (Aug. 27, 2019) (proposed SNUR)	Direct final SNUR withdrawn Oct. 24, 2018. Proposed SNUR under review.	§ 5(e) order: “Further, if the polymer were made differently there could be other hazards. For example, if made differently, there could be free isocyanates. See [Diisocyanate Chemicals Category ...]	No	“It is a significant new use to manufacture the chemical substance containing greater than 0.1 percent residual isocyanate or an average molecular weight below 1,000 daltons.”

P-17-24	<p>Proposed 40 C.F.R § 721.11159</p> <p>83 Fed. Reg. 49806 (Oct. 3, 2018) (direct final SNUR); 83 Fed. Reg. 49903 (Oct. 3, 2019) (proposed SNUR)</p>	<p>Direct final SNUR withdrawn Dec. 4, 2018. Proposed SNUR under review.</p>	<p>§ 5(f) order: “Respiratory and dermal sensitization and lung and mucous membrane irritation based on the isocyanate moiety Diisocyanates are well-known dermal, eye, and inhalation irritants and sensitizers based on worker data. They have been documented in the workplace to cause asthma and respiratory problems, such as hypersensitivity pneumonitis, an inflammation of the lungs. In severe cases, there have been reported fatal reactions Isocyanate exposure has been identified as the leading attributable cause of work-related asthma, and prevalence in the exposed workforce has been estimated at 1-20 percent (see Refs. 1 and 2). Once a worker is sensitized to diisocyanates, subsequent exposures can trigger severe asthma attacks. Spray application and heated processes are associated with higher incidences of asthma than other application methods because they can generate airborne isocyanate vapors and mists, which lead to worker exposure via the respiratory and dermal routes. Most workers who develop diisocyanate asthma have experienced long periods of exposure (months or longer); however, the minimum exposure to isocyanates that can elicit sensitization responses or asthma is unknown. In addition, immune response and subsequent disease in humans can vary significantly</p>	No	No
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PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
			between individuals (Ref. 3). Fatalities linked to diisocyanate exposures in sensitized persons have been reported (Refs. 4 and 5.) More information on isocyanate effects, could be found in the Diisocyanate Chemicals Category ...; or in the publication from Department of Health and Human Services, Center for Disease Control 'NIOSH Alert on Preventing Asthma and Death from MDI Exposure During Spray-on Truck Bed Liner and Related Applications'”		
P-17-25	Proposed 40 C.F.R. § 721.11160 83 Fed. Reg. 49806 (Oct. 3, 2018) (direct final SNUR); 83 Fed. Reg. 49903 (Oct. 3, 2019) (proposed SNUR)	Direct final SNUR withdrawn Dec. 14, 2018. Proposed SNUR under review.	Same as above	No	No

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-17-10	Proposed 40 C.F.R. § 721.11084 83 Fed. Reg. 40986 (Aug. 17, 2018) (direct final SNUR); 83 Fed. Reg. 41039 (Aug. 17, 2018) (proposed SNUR)	Direct final SNUR withdrawn Oct. 11, 2018. Proposed SNUR under review.	§ 5(e) order: None specifically identified as attributable to isocyanates.	No	“It is a significant new use to manufacture the chemical substance with an average molecular weight below 2,000 daltons or containing greater than 0.1% residual isocyanate.”

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-16-493	Proposed 40 C.F.R. § 721.11125 83 Fed Reg. 47004 (Sept. 17, 2018) (direct final SNUR); 83 Fed. Reg. 47026 (Sept. 17, 2018) (proposed SNUR)	Direct final SNUR withdrawn Nov. 16, 2018. Proposed SNUR under review.	§ 5(e) order: “Basis: Diisocyanates Chemicals Category NIOSH Alert on Preventing Asthma and Death from MDI Exposure During Spray-on Truck Bed Lining and Related Applications Due to the possibility of isocyanate residuals there is concern for sensitization. Exposure to diisocyanate may cause the following effects: skin irritation and allergic reaction, respiratory irritation, respiratory sensitization, and lung toxicity; some diisocyanates also may cause cancer. It is especially important to note that contact with the skin may lead to respiratory sensitization or cause other allergic reactions.”	No, but the section 5(e) order cautioned, “Inhalation exposure should be limited to < 0.05 mg/m ³ as an 8-hours time-weighted average (TWA) for combined polyisocyanates and diisocyanates.”	“It is a significant new use to import the PMN substance to contain more than 0.1% residual isocyanate by weight.”

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-16-363	Proposed 40 C.F.R. § 721.11101 83 Fed. Reg. 43538 (Aug. 27, 2018) (direct final SNUR); 83 Fed. Reg. 63607 (Aug. 27, 2018) (proposed SNUR)	Direct final SNUR withdrawn Oct. 24, 2018. Proposed SNUR under review.	§ 5(e) order: “Toxicological Endpoints of Concern: irritation to all moist tissues and sensitization. Basis: Diisocyanate Chemicals Category NIOSH Alert on Preventing Asthma and Death from MDI Exposure During Spray-on Truck Bed Liner and Related Applications.... Also, there are concerns for lung toxicity based on cationic binding to the lung tissue.”	No	“It is a significant new use to manufacture, process, or use the substance with a residual of free isocyanate monomers greater than 0.1 percent by weight.”
P-16-99	Proposed 40 C.F.R. § 721.11098 83 Fed. Reg. 43538 (Aug. 27, 2018) (direct final SNUR); 83 Fed. Reg. 63607 (Aug. 27, 2018) (proposed SNUR)	Direct final SNUR withdrawn Oct. 24, 2018. Proposed SNUR under review.	§ 5(e) order: None specifically identified as attributable to isocyanates.	NCEL = 0.9 mg/m ³ TWA ₈	“It is a significant new use to manufacture the chemical substance containing greater than 0.2% residual isocyanate.”

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-15-707	Proposed 40 C.F.R. § 721.11030 83 Fed. Reg. 37702 (Aug. 1, 2018) (direct final SNUR); 83 Fed. Reg. 37455 (Aug. 1, 2018) (proposed SNUR)	Direct final SNUR withdrawn Oct. 11, 2018. Proposed SNUR under review.	None in the § 5(e) order. The SNUR preamble states: “There are also concerns ... for sensitization if there are residual isocyanates.”	NCEL = 0.9 mg/m ³ TWA ₈	“A significant new use is any manufacture, processing, or use of the PMN substance with more than 1% residual isocyanate by weight.” [Note: “1%” may be an error; the preamble refers to “manufacture of the PMN substance to contain no more than 0.1% isocyanate by weight.”]
P-15-706	Proposed 40 C.F.R. § 721.11029 83 Fed. Reg. 37702 (Aug. 1, 2018) (direct final SNUR); 83 Fed. Reg. 37455 (Aug. 1, 2018) (proposed SNUR)	Direct final SNUR withdrawn Oct. 11, 2018. Proposed SNUR under review.	§ 5(e) order: None specifically identified as attributable to isocyanates. The SNUR preamble states: “There are also concerns ... for sensitization if there are residual isocyanates.”	NCEL = 0.9 mg/m ³ TWA ₈	“A significant new use is any manufacture, processing, or use of the PMN substance with more than 0.1% residual isocyanate by weight.”

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-15-559	Proposed 40 C.F.R. § 721.10920 81 Fed. Reg. 30452 (May 16, 2016) (direct final SNUR); 81 Fed. Reg. 74755 (Oct. 27, 2016) (proposed SNUR)	Direct final SNUR withdrawn July 14, 2016. Proposed SNUR under review.	No § 5(e) order – this is a non-order SNUR. Proposed SNUR preamble: “Based on SAR analysis of analogous diisocyanates, EPA identified concerns for potential dermal and respiratory sensitization from dermal and inhalation exposures, and for pulmonary toxicity from inhalation exposure, to the PMN substance where the average molecular weight is below 7,500 daltons and any molecular weight species is below 1,000 daltons EPA has determined, however, that any manufacture of the PMN substance with an average molecular weight below 7,500 daltons, and where any molecular weight species is below 1,000 daltons may cause serious health effects. For new isocyanates submitted as PMNs, EPA expects to issue TSCA section 5(e) orders imposing 0.1% limits on total residual isocyanates and greater levels of respiratory protection (at least an APF of 50, or 1000 if used in a process that generates a vapor or particulate), and no consumer use. The Agency would then likely issue a SNUR defining the significant new use as total residual isocyanates exceeding that 0.1% limit and any use in a consumer product.”	No	“A significant new use of the substance is manufacture of the substance where the average molecular weight is below 7,500 daltons, and where any molecular weight species is below 1,000 daltons.”

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-15-378	Proposed 40 C.F.R. § 721.10913 Direct final SNUR, 81 Fed. Reg. 30452 (May 16, 2016); proposed SNUR, 81 Fed. Reg. 74755 (Oct. 27, 2016)	Direct final SNUR withdrawn July 14, 2016. Proposed SNUR under review.	No § 5(e) order – this is a non-order SNUR. Proposed SNUR preamble: “Based on SAR analysis of test data on analogous diisocyanates, EPA identified concerns for respiratory sensitization.”	No	No
P-15-278	Proposed 40 C.F.R. § 721.10874 80 Fed. Reg. 59583 (Oct. 2, 2015) (direct final SNUR); 81 Fed. Reg. 21830 (Apr. 13, 2016) (proposed SNUR)	Direct final SNUR withdrawn Nov. 20, 2015. Proposed SNUR under review.	No § 5(e) order – this is a non-order SNUR. SNUR preamble: “Based on analogous diisocyanates, EPA identified concerns for potential dermal and respiratory sensitization from dermal and inhalation exposures, and for pulmonary toxicity from inhalation exposure, to the PMN substance when the average molecular weight is below 2500 daltons and any molecular weight species is below 1000 daltons.”	No	“The significant new use is manufacture of the substance where the average molecular weight is below 2,500 daltons and where any molecular weight species is below 1,000 daltons.”

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-15-247	Proposed 40 C.F.R. § 721.10873 80 Fed. Reg. 59583 (Oct. 2, 2015) (direct final SNUR); 81 Fed. Reg. 21830 (Apr. 13, 2016) (proposed SNUR)	Direct final SNUR withdrawn Nov. 11, 2015. Proposed SNUR under review.	No § 5(e) order – this is a non-order SNUR. SNUR preamble: “Based on SAR analysis of test data on analogous diisocyanates, EPA identified concerns for respiratory and dermal sensitization and lung and mucous membrane irritation based on the isocyanate moiety.”	No	No
P-15-221	Proposed 40 C.F.R. § 721.10871 80 Fed. Reg. 59583 (Oct. 2, 2015) (direct final SNUR); 81 Fed. Reg. 21830 (Apr. 13, 2016) (proposed SNUR)	Direct final SNUR withdrawn Nov. 20, 2015. Proposed SNUR under review.	No § 5(e) order – this is a non-order SNUR. SNUR preamble: “Based on SAR analysis of test data on analogous diisocyanates, EPA identified concerns for irritation and sensitization to the skin and lungs.”	No	No

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-14-357	Direct final SNUR, 40 C.F.R. § 721.10788 79 Fed. Reg. 63821 (Oct. 27, 2014)	Effective Dec. 26, 2014.	No § 5(e) order – this is a non-order SNUR. SNUR preamble: “Based on SAR analysis of test data on analogous diisocyanates, EPA identified concerns for dermal and respiratory sensitization.”	No	No
P-14-60	Proposed 40 C.F.R. § 721.10762 79 Fed. Reg. 38464 (July 8, 2014) (direct final SNUR); 80 Fed. Reg. 858 (Jan. 9, 2015) (proposed SNUR)	Direct final SNUR withdrawn Sept. 4, 2014. Proposed SNUR under review.	No § 5(e) order – this is a non-order SNUR. SNUR preamble: “Based on SAR analysis of test data on analogous diisocyanates, EPA identified concerns for dermal and respiratory sensitization to persons exposed to the PMN substance.”	No	No

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-13-619	Proposed 40 C.F.R. § 721.10744 79 Fed. Reg. 39268 (July 9, 2014) (direct final rule); 80 Fed. Reg. 858 (Jan. 7, 2015) (proposed SNUR)	Direct final SNUR withdrawn Sept. 4, 2014. Proposed SNUR under review.	No § 5(e) order – this is a non-order SNUR. SNUR preamble: “Based on SAR analysis of test data on analogous diisocyanates, EPA identified concerns for respiratory sensitization.”	No	No
P-13-618	Proposed 40 C.F.R. § 721.10743 79 Fed. Reg. 39268 (July 9, 2014) (direct final rule); 80 Fed. Reg. 858 (Jan. 7, 2015) (proposed SNUR)	Direct final SNUR withdrawn Sept. 4, 2014. Proposed SNUR under review.	No § 5(e) order – this is a non-order SNUR. SNUR preamble: “Based on SAR analysis of test data on analogous diisocyanates, EPA identified concerns for respiratory sensitization.”	No	No

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-13-617	Proposed 40 C.F.R. § 721.10742 79 Fed. Reg. 39268 (July 9, 2014) (direct final rule); 80 Fed. Reg. 858 (Jan. 7, 2015) (proposed SNUR)	Direct final SNUR withdrawn Sept. 4, 2014. Proposed SNUR under review.	No § 5(e) order – this is a non-order SNUR. SNUR preamble: “Based on SAR analysis of test data on analogous diisocyanates, EPA identified concerns for respiratory sensitization.”	No	No
P-13-563	Proposed 40 C.F.R. § 721.10741 79 Fed. Reg. 39268 (July 9, 2014) (direct final rule); 80 Fed. Reg. 858 (Jan. 7, 2015) (proposed SNUR)	Direct final SNUR withdrawn Sept. 4, 2014. Proposed SNUR under review.	No § 5(e) order – this is a non-order SNUR. SNUR preamble: “Based on SAR analysis of analogous diisocyanates, EPA identified concerns for oncogenicity, mutagenicity, respiratory and dermal sensitization and lung and mucous membrane irritation from exposure to the PMN substance via inhalation and dermal exposures.”	No	No

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-13-559	40 C.F.R. § 721.10795 80 Fed. Reg. 5457 (Feb. 2, 2015) (direct final SNUR)	Effective Apr. 3, 2015.	No § 5(e) order – this is a non-order SNUR. None specifically identified in SNUR preamble as attributable to isocyanates.	No	No
P-13-471	Proposed 40 C.F.R. § 721.10723 79 Fed. Reg. 8273 (Feb. 12, 2014) (direct final SNUR); 80 Fed. Reg. 845 (Jan. 7, 2015) (proposed SNUR)	Direct final SNUR withdrawn Apr. 14, 2014. Proposed SNUR under review.	No § 5(e) order – this is a non-order SNUR. SNUR preamble: “Based on test data on analogous diisocyanates, EPA identified concerns for oncogenicity, mutagenicity, respiratory and dermal sensitization, and lung and mucous membrane irritation to workers exposed to the PMN substance.”	No	No

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-13-393	Proposed 40 C.F.R. § 721.10720 79 Fed. Reg. 8273 (Feb. 12, 2014) (direct final SNUR); 80 Fed. Reg. 845 (Jan. 7, 2015) (proposed SNUR)	Direct final SNUR withdrawn Apr. 14, 2014. Proposed SNUR under review.	No § 5(e) order – this is a non-order SNUR. SNUR preamble: “Based on test data on analogous diisocyanates, the Agency identified concerns for dermal and respiratory sensitization, irritation to all moist tissues, and lung effects if inhaled based on the low molecular weight isocyanates.”	No	No
P-13-392	Proposed 40 C.F.R. § 721.10719 79 Fed. Reg. 8273 (Feb. 12, 2014) (direct final SNUR); 80 Fed. Reg. 845 (Jan. 7, 2015) (proposed SNUR)	Direct final SNUR withdrawn Jan. 14, 2014. Proposed SNUR under review.	No § 5(e) order – this is a non-order SNUR. SNUR preamble: “EPA identified concerns for dermal and respiratory sensitization, irritation to all moist tissues, and lung effects if inhaled based on the low molecular weight isocyanates, to workers exposed to the PMN substance.”	No	No

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-13-365	Proposed 40 C.F.R. § 721.10717 79 Fed. Reg. 8273 (Feb. 12, 2014) (direct final SNUR); 80 Fed. Reg. 845 (Jan. 7, 2015) (proposed SNUR)	Direct final SNUR withdrawn Apr. 14, 2014. Proposed SNUR under review.	No § 5(e) order – this is a non-order SNUR. SNUR preamble: “Based on test data on analogous diisocyanates, EPA identified concerns for dermal and respiratory sensitization, and lung and mucous membrane irritation effects.”	No	No
P-13-357	40 CF.R. § 721.10788 78 Fed. Reg. 63821 (Oct. 27, 2014)	Effective Dec. 26, 2014	No § 5(e) order – this is a non-order SNUR. SNUR preamble: “Based on SAR analysis of test data on analogous diisocyanates, EPA identified concerns for irritation to the eye, skin, and mucous membranes; and dermal and respiratory sensitization.”	No	No
P-13-338	40 CF.R. § 721.10693 78 Fed. Reg. 48059 (Aug. 7, 2013)	Effective Oct. 7, 2013.	No § 5(e) order – this is a non-order SNUR. SNUR preamble: “Based on analogous diisocyanates, EPA identified concerns for dermal and respiratory sensitization, irritation, and lung effects.”	No	No

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-13-232	40 C.F.R. § 721.10690 78 Fed. Reg. 48059 (Aug. 7, 2013) (direct final SNUR)	Effective Oct. 7, 2013.	No § 5(e) order – this is a non-order SNUR. SNUR preamble: “Based on analogous diisocyanates, EPA identified concerns for sensitization as well as lung and mucous membrane irritation.”	No	No
P-13-176	40 C.F.R. § 721.10773 79 Fed. Reg. 63821 (Oct. 27 2014) (direct final SNUR)	Effective Dec. 26, 2014	No § 5(e) order – this is a non-order SNUR. None specifically identified in SNUR preamble as attributable to isocyanates.	No	No
P-13-175	40 C.F.R. § 721.10772 79 Fed. Reg. 63821 (Oct. 27, 2014) (direct final SNUR)	Effective Dec. 26, 2014	No § 5(e) order – this is a non-order SNUR. None specifically identified in SNUR preamble as attributable to isocyanates.	No	No
P-12-373	40 C.F.R. § 721.10626 77 Fed. Reg. 66149 (Nov. 2, 2012) (direct final SNUR)	Effective Jan. 2, 2013	No § 5(e) order – this is a non-order SNUR. SNUR preamble: “Based on test data on analogous acrylates and isocyanates, EPA identified concerns for respiratory and dermal sensitization and irritation to workers from exposure to the PMN substance.”	No	No

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-12-326	40 C.F.R. § 721.10624 77 Fed. Reg. 66149 (Nov. 2, 2012) (direct final SNUR)	Effective Jan. 2, 2013	No § 5(e) order – this is a non-order SNUR. SNUR preamble: “Based on analogous diisocyanate substances, EPA identified concerns for potential dermal and respiratory sensitization from dermal and inhalation exposures, and for pulmonary toxicity from inhalation exposure to the PMN substance. Specifically, the Agency expects potential toxicity to workers from dermal or inhalation exposure to the PMN substance when the molecular weight is less than 1000 daltons.”	No	“The significant new uses are: (i) Industrial, commercial, and consumer activities. Requirements as specified in § 721.80(j) (manufacture, processing, or use where the molecular weight is 1000 daltons or more).” [Note: presumably should be 1000 daltons or less.]
P-12-274	40 C.F.R. § 721.10660 79 Fed. Reg. 51899 (Sept. 2, 2014) (final SNUR); 78 Fed. Reg. 12684 (Feb. 25, 2013) (proposed SNUR)	Effective Nov. 3, 2014	No § 5(e) order – this is a non-order SNUR. Proposed SNUR preamble: “Based on SAR analysis of test data on analogous isocyanates, EPA identified concern for sensitization from dermal and inhalation exposure to the PMN substance.”	No	No

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-12-143	40 C.F.R. § 721.10659 79 Fed. Reg. 51899 (Sept. 2, 2014) (final SNUR); 78 Fed. Reg. 12684 (Feb. 25, 2013) (proposed SNUR)	Effective Nov. 3, 2014	No § 5(e) order – this is a non-order SNUR. Proposed SNUR preamble: “Based on SAR analysis of test data on analogous isocyanates, EPA identified concerns for sensitization from dermal and respiratory exposures to the PMN substance.”	No	No
P-12-133	40 C.F.R. § 721.10658 79 Fed. Reg. 51899 (Sept. 2, 2014) (final SNUR); 78 Fed. Reg. 12684 (Feb. 25, 2013) (proposed SNUR)	Effective Nov. 3, 2014	No § 5(e) order – this is a non-order SNUR. Proposed SNUR preamble: “based on the isocyanate moiety, the Agency identified concerns for sensitization.”	No	No

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-12-73	40 C.F.R. § 721.10657 79 Fed. Reg. 51899 (Sept. 2, 2014) (final SNUR); 78 Fed. Reg. 12684 (Feb. 25, 2013) (proposed SNUR)	Effective Nov. 3, 2014	No § 5(e) order – this is a non-order SNUR. Proposed SNUR preamble: “Based on SAR analysis of test data on analogous diisocyanates, EPA identified concerns for sensitization.”	No	No
P-11-862	40 C.F.R. § 721.10298 77 Fed. Reg. 20296 (Apr. 4, 2012) (direct final SNUR)	Effective June 4, 2012	No § 5(e) order – this is a non-order SNUR. SNUR preamble: “Based on test data on analogous diisocyanates, EPA identified concerns for mutagenicity, irritation to lungs and mucous membranes, and dermal and respiratory sensitization to workers from dermal and inhalation exposure to the PMN substance.”	No	No

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-11-314	40 C.F.R. § 721.10656 79 Fed. Reg. 51899 (Sept. 2, 2014) (final SNUR); 78 Fed. Reg. 12684 (Feb. 25, 2013) (proposed SNUR)	Effective Nov. 3, 2014	No § 5(e) order – this is a non-order SNUR. Proposed SNUR preamble: “Based on SAR analysis of test data on analogous isocyanates, EPA identified concerns for sensitization from dermal and inhalation exposure to the PMN substances.”	No	No
P-11-313	40 C.F.R. § 721.10655 79 Fed. Reg. 51899 (Sept. 2, 2014) (final SNUR); 78 Fed. Reg. 12684 (Feb. 25, 2013) (proposed SNUR)	Effective Nov. 3, 2014	No § 5(e) order – this is a non-order SNUR. Proposed SNUR preamble: “Based on SAR analysis of test data on analogous isocyanates, EPA identified concerns for sensitization from dermal and inhalation exposure to the PMN substances.”	No	No

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-11-312	40 C.F.R. § 721.10654 79 Fed. Reg. 51899 (Sept. 2, 2014) (final SNUR); 78 Fed. Reg. 12684 (Feb. 25, 2013) (proposed SNUR)	Effective Nov. 3, 2014	No § 5(e) order – this is a non-order SNUR. Proposed SNUR preamble: “Based on SAR analysis of test data on analogous isocyanates, EPA identified concerns for sensitization from dermal and inhalation exposure to the PMN substances.”	No	No
P-11-311	40 C.F.R. § 721.10653 79 Fed. Reg. 51899 (Sept. 2, 2014) (final SNUR); 78 Fed. Reg. 12684 (Feb. 25, 2013) (proposed SNUR)	Effective Nov. 3, 2014	No § 5(e) order – this is a non-order SNUR. Proposed SNUR preamble: “Based on SAR analysis of test data on analogous isocyanates, EPA identified concerns for sensitization from dermal and inhalation exposure to the PMN substances.”	No	No

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-11-309	40 C.F.R. § 721.10652 79 Fed. Reg. 51899 (Sept. 2, 2014) (final SNUR); 78 Fed. Reg. 12684 (Feb. 25, 2013) (proposed SNUR)	Effective Nov. 3, 2014	No § 5(e) order – this is a non-order SNUR. Proposed SNUR preamble: “Based on SAR analysis of test data on analogous isocyanates, EPA identified concerns for sensitization from dermal and inhalation exposure to the PMN substances.”	No	No
P-11-115	40 C.F.R. § 721.10649 79 Fed. Reg. 51899 (Sept. 2, 2014) (final SNUR); 78 Fed. Reg. 12684 (Feb. 25, 2013) (proposed SNUR)	Effective Nov. 3, 2014	No § 5(e) order – this is a non-order SNUR. Proposed SNUR preamble: “Based on SAR analysis of test data on analogous diisocyanates, EPA identified concerns for respiratory and dermal sensitization.”	No	No

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-11-60	40 C.F.R. § 721.10661 78 Fed. Reg. 27048 (May 9, 2013) (direct final SNUR)	Effective July. 8, 2013.	No § 5(e) order – this is a non-order SNUR. SNUR preamble: “Based on structural activity relationship (SAR) analysis of test data on analogous diisocyanates, EPA identified concerns for dermal and respiratory sensitization and for pulmonary toxicity to workers exposed to free isocyanates.”	No	No
P-08-611	40 C.F.R. § 721.10571 77 Fed. Reg. 61118 (Oct. 5, 2012) (direct final SNUR)	Effective Dec. 4, 2012.	No § 5(e) order – this is a non-order SNUR. SNUR preamble: “Based on SAR analysis of test data on analogous diisocyanates, EPA identified concerns for dermal and respiratory sensitization and for pulmonary toxicity to workers exposed to free isocyanates.”	No	Significant new use is manufacture other than as described in the PMN, “(manufacture with all isocyanate groups reacted within the polymer).”
P-04-834	40 C.F.R. § 721.10490 77 Fed. Reg. 58666 (Sept. 21, 2012) (direct final rule)	Effective Nov. 20, 2012	§ 5(e) order unavailable. Direct final SNUR preamble: “Based on test data on analogous diisocyanates, EPA identified concerns for dermal and respiratory sensitization, pulmonary toxicity, and carcinogenicity from dermal and inhalation exposures.”	NCEL = 0.05 mg/m ³ TWA ₈	No

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-04-640	40 C.F.R. § 721.10643 79 Fed. Reg. 51899 (Sept. 2, 2014) (final SNUR); 78 Fed. Reg. 12684 (Feb. 25, 2013) (proposed SNUR)	Effective Nov. 3, 2014	§ 5(e) order unavailable. Proposed SNUR preamble: “Based on SAR analysis of test data on structurally similar diisocyanates, EPA identified concerns for dermal sensitization, respiratory sensitization, and pulmonary toxicity from exposure to the PMN substance by the inhalation and dermal routes.”	No	No
P-04-563	40 C.F.R. § 721.10343 77 Fed. Reg. 25236 (Apr. 27, 2012)	Effective June 26, 2012	No § 5(e) order – this is a non-order SNUR. SNUR preamble: None specifically identified as attributable to isocyanates.	No	No
P-03-767	40 C.F.R. § 721.10331	Effective June 26, 2012	No § 5(e) order – this is a non-order SNUR. SNUR preamble: None specifically identified as attributable to isocyanates.	No	No

PMN No.	C.F.R. Citation / F.R. Citation	Status of SNUR	Preamble Statement re Isocyanates	New Chemical Exposure Limit (NCEL)?	Special Restrictions in SNUR?
P-03-762 and P-03-763	40 C.F.R. § 721.10642 79 Fed. Reg. 51899 (Sept. 2, 2014) (final SNUR); 78 Fed. Reg. 12684 (Feb. 25, 2013) (proposed SNUR)	Effective Nov. 3, 2014	No § 5(e) order – this is a non-order SNUR. Proposed SNUR preamble: “Based on SAR analysis of test data on analogous isocyanates, EPA has identified concerns for sensitization and irritation from dermal and inhalation exposure to the PMN substances.”	No	No

Attachment 2

Isocyanates Are Not a Leading Cause of Occupational Asthma

April 5, 2019

Isocyanates Are Not a Leading Cause of Occupational Asthma

EPA has asserted multiple times that:

Isocyanate exposure has been identified as the leading attributable cause of work-related asthma, and prevalence in the exposed workforce has been estimated at 1-20%

This statement was not accurate when originally made, and it has become increasingly inaccurate with time. This paper first summarizes EPA's extensive reliance on the statement quoted above. Next, it reviews the sources on which the quoted statement relies and shows that those sources do not support the statement. It ends with a review of recent evidence that isocyanates are not now a significant cause of occupational asthma and have a low incidence rate.

In light of this evidence, EPA should stop referring to isocyanates as the leading attributable cause of occupational asthma. It should also stop referring to outdated and misleading incidence rates of isocyanate-related asthma.

1. EPA Has Repeatedly Referred to Isocyanates as the Leading Cause of Occupational Asthma, With Incidence of Up to 20%

In April 2011, EPA posted a Methylene Diphenyl Diisocyanate (MDI) And Related Compounds Action Plan and a Toluene Diisocyanate (TDI) And Related Compounds Action Plan. Both action plans asserted (p. 4):

It is well documented that isocyanate exposure is the leading cause of work-related asthma, and prevalence in the exposed workforce is estimated at 1-20% (Ott et al., 2003;¹ Bello et al., 2004).²

EPA repeated that statement in its proposed SNUR for TDI, 80 Fed. Reg. 2068, 2070 (Jan. 15, 2015):

Isocyanate exposure has been identified as the leading attributable cause of work-related asthma, and prevalence in the exposed workforce has been estimated at 1–20 percent (Refs. 11 and 12).³

¹ The citation for the Ott et al. paper is Ott MG, Diller, WF, Jolly AT. 2003. Respiratory Effects of Toluene Diisocyanates in the Workplace; a Discussion of Exposure-Response Relationships. *Critical Review Toxicology* 33:1-59.

² The citation for the Bello et al. paper is Bello D, Woskie SR, Streicher RP, Liu Y, Stowe MH, Eisen EA, Ellenbecker MJ, Sparer J, Youngs F, Cullen MR, Redlich CA. 2004. Polyisocyanates in Occupational Environments: a Critical Review of Exposure Limits and Metrics. *American Journal Industrial Medicine* 46:480-491.

³ Reference 11 and 12 are to the Ott et al. and Bello et al. papers cited above.

The statement appeared again in EPA's 2017 section 5(f) order for two new isocyanate-based polymers, P-17-24 and P-17-25. It stated (p. vii):

Isocyanate exposure has been identified as the leading attributable cause of work-related asthma, and prevalence in the exposed workforce has been estimated at 1-20 percent (see Refs. 1 and 2).⁴

In addition, EPA has issued several section 5(e) orders⁵ for other new isocyanate-based polymers that refer to the 2006 NIOSH Alert, "Preventing Asthma and Death from MDI Exposure During Spray-on Truck Bed Liner and Related Applications," which states (p. 4):

Isocyanates are the leading attributable chemical cause of occupational asthma in the United States and many other industrialized countries [Tarlo et al. 1997b].

With these statements reasserted so many times, it is likely that EPA relies on them for the restrictions it imposes on new isocyanate-based polymers it reviews under section 5 of TSCA. As demonstrated in section 2 below, the statements were not accurate at the time they were originally made. As demonstrated in section 3 below, the statements are even less accurate now.

2. The Cited References Do Not Support the EPA Statements

The sources on which EPA relied for the statements noted in section 1 are more than 10 years old. They relied in turn on older papers, which cited even older papers. The Ott et al., Bello et al., and Tarlo et al. papers do not support the statements repeated by EPA.

a. Ott et al. (2003)

The 2003 Ott et al. paper, now 16 years old, was a literature review, not a primary source. It presented a very different perspective than that cited by EPA:

In the early years of the industry, annual incidence rates of occupational asthma (OA) due to TDI ranged from 1% to as high as 6%, depending on the extent of engineering and work practice controls in the various workplaces. **Since the mid-1970s, annual OA incidence rates have been < 1%**, where 8 h TDI concentrations have been maintained below 5 ppb as determined by personal monitoring, even where short-term TDI concentrations above 20 ppb and less frequently above 40 ppb were routinely detected. [Emphasis added.]

The paper did say that "diisocyanates are among the most prevalent reported causes of OA." It did not mention a 20% incidence rate, however.

b. Bello et al. (2004)

⁴ References 1 and 2 are to the Ott et al. and Bello et al. papers cited above.

⁵ Including the section 5(e) orders for PMNs P-17-231, P-17-222, P-17-24 and -25, 16-493, and 16-393.

This paper did use a 20% incidence figure for sensitization and asthma together (i.e., not specifically for asthma), citing other older studies of which none suggested an incidence rate of 20%:

However, sensitization and asthma are the primary health concerns, and **their estimated prevalence in the exposed workforce is 1-20%** [Vandenplas et al., 1993a; Bernstein, 1996; Petsonk et al., 2000; Wisnewski and Redlich, 2001; Diller, 2002]. [Emphasis added.]

The cited papers do not support the Bello et al. statement of an incidence rate of up to 20%.

The 1993 Vandenplas et al. paper,⁶ itself a literature review and now 26 years old, did not support a 20% incidence figure. It stated:

According to the results of studies with objective diagnostic tests, a **prevalence of about 10%** seems to be a reasonable approximation. [Citations omitted, emphasis added.]

It did state that “isocyanates are the principal cause of occupational asthma,” citing a 1984 paper by Davies (now 35 years old). The Davies paper did not summarize surveillance data; it included only the author’s opinion.

The 1996 Bernstein et al. paper⁷ was also a literature review and is now 23 years old. It did not suggest a ranking of the leading causes of occupational asthma. The paper suggested a prevalence of 5 to 10%:

Surveillance programs established around the world have determined that diisocyanate chemicals are the most common cause of occupational asthma. In the United States approximately 100,000 workers are exposed to these chemical compounds in the workplace each year and **5-10% of these workers will develop occupational asthma**. [Emphasis added.]

The 2000 Petsonk et al. paper,⁸ now 19 years old, did not indicate the ranking of diisocyanates with other causes of occupational asthma. It indicated a “low prevalence” where exposures are controlled:

Diisocyanates, a group of highly reactive chemicals, have been frequently associated with the new onset of asthma in relation to work exposures, although in industrial settings in which exposures to these chemicals are well controlled, **a low prevalence of symptoms has been reported**. [Emphasis added.]

⁶ The citation is Vandenplas O, Malo JL, Saetta M, Mapp CE, Fabbri LM. 1993. Occupational asthma and extrinsic alveolitis due to isocyanates; current status and perspectives. Br J Ind Med 50:213-228.

⁷ The citation is Bernstein, JA. 1996. Overview of diisocyanate occupational asthma. Toxicology 111(1-3):181-189.

⁸ The citation is Petsonk EL, Wang ML, Lewis DM, Siegel PD, Husberg BJ. 2000. Asthma-like symptoms in wood product plant workers exposed to methylene diphenyl diisocyanate. Chest 118:1183-1193.

The 2001 Wisnewski and Redlich paper,⁹ now 18 years old, referenced 11 papers in stating, “Diisocyanates are one of the most commonly identified causes of occupational asthma.” However, only one of the references, a 1999 paper by Jajosky et al.¹⁰ (now 20 years old), actually ranked the causes. Using data from 1993-1995 (24 to 26 years ago), it listed TDI as number 8 (3.7% of cases); diisocyanates NOS as number 10 (3.3% of cases); and MDI as number 15 (2.4% of cases).

The Wisnewski and Redlich paper estimated prevalence of isocyanate-caused occupational asthma at between 5 and 15%, citing earlier papers.

The 2002 Diller paper¹¹ (now 17 years old) did not refer to isocyanates as the leading cause of occupational asthma. Instead, in referencing a 1993 book (now 26 years old), it said:

In recent years, occupational asthma (OA) has become the most frequent occupational lung disease in many countries. Among the many agents that may cause OA, the isocyanates have gained wide attention.

The Diller paper indicated that incidence of TDI-caused occupational asthma was between 0 and 10% as of 2002:

Prevalence of occupational asthma due to toluene diisocyanate can be estimated from 10 cross-sectional studies, based on 788 persons. Prevalence had repeatedly been above 10 percent before 1985, and have been mostly between zero and 10 percent in recent years.

It added:

According to general surveillance schemes, compensation statistics, and disease registers, the annual case numbers of OA due to all types of isocyanates also show a downward trend in most countries during recent years, in spite of steadily increasing production and use of all isocyanates.

In short, the sources cited in the 2003 Ott et al. paper and the 2004 Bello et al. paper do not support the assertions that EPA has repeatedly made.

⁹ The citation is Wisnewski AV, Redlich CA. 2001. Recent developments in diisocyanate asthma. *Curr Opin Allergy Clin Immunol* 1:169-175.

¹⁰ The citation is Jajosky RA, Harrison R, Reinisch F, et al. Surveillance of work-related asthma in selected US states using surveillance guidelines for state health departments ± California, Massachusetts, Michigan, and New Jersey, 1993-1995. *Morb Mortal Weekly Rep CDC Surveillance Summaries* 1999; 48:1-20.

¹¹ The citation is Diller WF. 2002. Frequency and trends of occupational asthma due to toluene diisocyanate: A critical review. *Appl Occup Environ Hyg* 17:872-877.

c. **Tarlo et al. (1997)**

The 2006 NIOSH Alert cited only Tarlo et al.¹² for its assertion that “isocyanates are the leading attributable chemical cause of occupational asthma in the United States and many other industrialized countries.” This 1997 article appeared 22 years ago. While ACC has not reviewed the full article, its abstract reports that the paper “provides some evidence that facilities having OA claims have higher isocyanate exposures than to those without claims.” This suggests that any statement about isocyanates being the leading attributable chemical cause of occupational asthma was supported only by references to even earlier papers, as was the case with the Ott et al. paper and the Bello et al. paper. These papers relied on evidence now more than two decades old. They do not reflect current incidence rates, as demonstrated below.

Notably, much more recently, Tarlo has co-authored two articles that reported substantial declines in the isocyanate-related occupational asthma cases. The 2011 article¹³ found:

In conclusion, the study suggests that there has been a reduction in absolute number of ISO and N-ISO OA allowed claims, with a somewhat greater relative decline of ISO OA claims.

The 2016 article¹⁴ stated:

The recent period included a significantly smaller proportion (of OA cases) employed in the manufacturing industry and isocyanate-induced cases compared with the earlier period.

It established that there have only been 3 cases of diisocyanate-related occupational asthma in the years 2010-2014 in Toronto, Canada.

Thus, EPA should not continue to rely on a 2006 NIOSH alert that cites a 22-year-old paper whose lead author has since written at least twice on the substantial decline in the incidence of isocyanate-related occupational asthma.

3. Current Information Shows That Isocyanates Are Not a Significant Cause of Occupational Asthma

The outdated references on which EPA relies for its misleading statements about isocyanates and occupational asthma do not reflect the sharp drop in incidence of isocyanate-related occupational asthma. Current information establishes that isocyanates are now a minor cause of occupational asthma.

¹² The citation is Tarlo SM, Liss GM, Dias C, Banks DE. 1997. Assessment of the relationship between isocyanate exposure levels and occupational asthma. *Am J Ind Mem* 32(5):517-5 21.

¹³ The citation is Buyantseva L, Liss GM, Ribeiro, Manno M, Luce CE, Tarlo SM. 2011. Reduction in Diisocyanate and Non-Diisocyanate Sensitizer-Induced Occupational Asthma in Ontario. *JOEM*. DOI: 10.1097/JOM.0b013e3182122376.

¹⁴ The citation is Gotzev G, Lipszyc JC, Connor D, Tarlo SM. 2016. Trends in Occupations and Work Sectors Among Patients With Work-Related Asthma at a Canadian Tertiary Care Clinic. *Chest*. 150(4):811-818.

The NIOSH website reports on most-frequently reported causes of occupational asthma for the period of 2009-2012 in four states. The leading cause was reported to be “miscellaneous chemicals and materials” (not including isocyanates), accounting for 22.4% of the cases. Isocyanates were the 19th most-frequently reported cause, accounting for just 1.0% of the cases. This information contradicts the assertion in the 2006 NIOSH Alert.

A 2017 paper by Collins et al.¹⁵ reported that “diisocyanates, such as toluene diisocyanate (TDI), are a cause of occupational asthma.” It then explains that incidence rates for TDI-induced asthma have declined:

There is evidence from surveillance reports of declining trends in occupational asthma during the 1990s in the United States, United Kingdom, Finland, and Canada. Reviews of workplace studies indicate also that incidence rates of TDI-induced asthma have declined. These favorable trends appear to be related to a reduction in workplace exposures through engineering controls and changes in work practices.

A 2015 paper by Stocks¹⁶ et al. made its own finding about declining incidence rates:

From 2006 to 2014, there was a significant decline in the number of urine samples with detectable levels of [a biomarker for exposure to 1,6-hexamethylene diisocyanate (HDI)] Over the same period, there was a significant decline in all asthma cases attributed to isocyanates or spray painting reported to SWORD ... and a non-significant decline among MVR workers

This paper attributed the decline to improved industrial hygiene methods:

The simultaneous decrease in HDI exposure and incident cases of asthma reported to SWORD is temporally consistent with a reduction in exposure to airborne isocyanate leading to a reduction in asthma. Although this is not direct evidence of a causal relationship between the two trends, it is suggestive.

Declines were noted even in papers from a decade earlier. As noted above, the 2003 Ott et al. paper reported:

In the early years of the industry, annual incidence rates of occupational asthma (OA) due to TDI ranged from 1% to as high as 6%, depending on the extent of engineering and work practice controls in the various workplaces. Since the mid-1970s, annual OA incidence rates have been < 1%, where 8 h TDI concentrations have been maintained below 5 ppb as determined by personal monitoring, even where short-term TDI concentrations above 20 ppb and less frequently above 40 ppb were routinely detected.

¹⁵ The citation is Collins JJ, Anteau S, Conner PR, Cassidy LD, Doney B, Wang ML, Kurth L, Carson M, Molenaar D, Redlich CA, Storey E. 2017. Incidence of Occupational Asthma and Exposure to Toluene Diisocyanate in the United States Toluene Diisocyanate Production Industry. JOEM 59(125):S22-S27.

¹⁶ The citation is Stocks SJ, Jones K, Piney M, Agius RM. 2015. Isocyanate exposure and asthma in the UK vehicle repair industry. Occupational Medicine 2015;65:713-718.

In addition to improved industrial hygiene practices, substitution of MDI for TDI may also have contributed to the decline in incidence of isocyanate-related asthma. A 2005 paper by Krone et al.¹⁷ noted:

Prior to 1980, most PUF [polyurethane foam] was produced using toluene diisocyanate (TDI). Post-1980, there was a shift to the use of methylenediphenyl diisocyanate (MDI) and pre-polymers of TDI (pre-reacted TDI polymer) MDI was introduced as a safer substitute for TDI in the manufacture of PU due to MDI's exceedingly low volatility¹⁸ and correspondingly low inhalation potential (less than 1 ppb on average).

Recent data compiled by ACC show a consistent picture of a decline in asthma rates associated with diisocyanates over the last decade, even as production rates of diisocyanates have increased. The reduction in diisocyanate-related occupational asthma is primarily due to a variety of product stewardship activities, including education and training, enhanced worker awareness, improved work practices, use of less volatile diisocyanate forms (e.g., pre-polymers), improved engineering controls (e.g., containment and/or ventilation), better medical surveillance programs, minimization of peak exposures, and continuing emphasis on compliance with existing exposure standards. These product stewardship efforts are key to further reductions in cases.

Conclusion

EPA's repeated statements about isocyanates being the leading cause of occupational asthma and incidence rates of isocyanate-related asthma as high as 20% are inaccurate and based on assessments primarily from the 1990s and earlier. They do not reflect changes in industrial hygiene practices and switching from TDI to MDI in many applications. Current evidence indicates that isocyanates are not a leading cause of occupational asthma. They account for 1% or less of occupational asthma cases.

Accordingly, EPA should stop repeating those statements. Instead, it should review current scientific literature. It should make its regulatory decisions under section 5 in light of current information, not on the basis of outdated and inaccurate papers.

¹⁷ The citation is Krone CA, Klinger TD. 2005. Isocyanates, polyurethane and childhood asthma. *Pediatric Allergy Immunol* 2005;16:368-379.

¹⁸ TDI has a vapor pressure of 0.01 mm Hg, whereas MDI has a vapor pressure of 0.000005 mm Hg, four orders of magnitude lower. See the NIOSH Pocket Guide to Chemical Hazards.

**AMERICAN CHEMISTRY COUNCIL
ENVIRONMENTAL PROTECTION AGENCY
MEETING AGENDA**

Date: Wednesday, April 10, 2019
Time: 8:00 – 9:00 am Eastern
Location: EPA East Building
1200 Constitution Avenue, NW
Washington, DC 20004

Time	Topic	Lead
8:00 a.m.	Administrative <ul style="list-style-type: none">• Introductions• Background• Purpose of Meeting	S. Osman-Sypher, ACC C. Franz, ACC
8:10 a.m.	Discuss ACC Questions on EPA's Approach to Isocyanate-Based Polymers Under Section 5 of TSCA	S. Osman-Sypher, ACC C. Franz, ACC
8:50 a.m.	Discuss Next Steps	S. Osman-Sypher, ACC C. Franz, ACC
9:00 a.m.	Adjournment	

ANTITRUST CHECKLIST FOR AMERICAN CHEMISTRY COUNCIL MEETINGS

This antitrust checklist, a part of ACC's Antitrust Compliance Guide, is for use by ACC staff and member company representatives in the conduct of ACC-sponsored meetings. Prohibited discussion topics apply equally to social gatherings incidental to ACC-sponsored meetings. The checklist is not exhaustive and does not address antitrust issues relating to activities other than ACC meetings. Participants in ACC meetings also should be thoroughly familiar with the Antitrust Compliance Guide.

DO

Do ensure strict performance in areas of:

OVERSIGHT/SUPERVISION:

- Have an ACC staff representative at each ACC-sponsored meeting;
- Consult with ACC counsel on all antitrust questions relating to ACC-sponsored meetings;
- Limit meeting discussions to agenda topics (unless additional topics have been approved by the ACC staff representative); and
- Provide each member company representative and ACC employee attending an ACC-sponsored meeting with a copy of this checklist, and have a copy available for reference at all ACC-sponsored meetings.

RECORDKEEPING:

- Have an agenda and minutes which accurately reflect the matters which occur; and
- Provide agendas and minutes to ACC legal counsel for review and approval in advance of distribution.

VIGILANCE:

- Protest against or stop any discussion or meeting activities which appear to violate this checklist. Member company representatives should disassociate themselves from any such discussion or activities and leave any meeting in which they continue.

DON'T

Don't, in fact or appearance, discuss or exchange information on:

PRICES, INCLUDING:

- Individual company prices, price changes, price differentials, markups, discounts, allowance, credit terms, etc.;
- Individual company data on costs, production, capacity, inventories, sales, etc.; and
- Industry pricing policies, price levels, price changes, differentials, etc.

PRODUCTION, INCLUDING:

- Plans of individual companies concerning the design, production, distribution or marketing of particular products, including proposed territories or customers; and
- Changes in industry production, capacity or inventories.

TRANSPORTATION RATES:

- Rates or rate policies for individual shipments, including basing point systems, zone prices, freight equalization, etc.

MARKET PROCEDURES, INCLUDING:

- Company bids on contracts for particular products; company procedures for responding to bid invitations; and
- Matters relating to actual or potential individual suppliers or customers that might have the effect of excluding them from any market or influencing the business conduct of firms toward them.

Message

From: Berger, Tom C. [Berger@khlaw.com]
Sent: 4/3/2019 12:39:35 PM
To: Bauer, Jeff [Bauer.Jeff@epa.gov]
CC: Daniels, Rhys G. [daniels@khlaw.com]; Schweer, Greg [Schweer.Greg@epa.gov]
Subject: RE: P-16-05X3

Jeff – thanks.

Here is a basic agenda for our call today at 11:00 ET:

- I. Self-Introductions
 - a. Keller and Heckman (PMN technical contact)
 - b. PMN Submitter
 - c. EPA
- II. Description of PMN, EPA Concerns
- III. Discussion of Product Needs and Paths to Commercialization
 - a. Testing and Protocols
 - i. Mammalian study
 - ii. Surface tension evaluation
 - iii. Particle size analysis
 - b. Respiratory protection
- IV. Pathforward, timing

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Friday, March 29, 2019 5:43 PM
To: Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Tom,
I set the meeting up for Wednesday April 3, at 11 am. RAD has accepted the invitation for that time.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

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1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Bauer, Jeff
Sent: Tuesday, March 26, 2019 11:37 AM
To: 'Berger, Tom C.' <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: P-16-05X3

Tom, I left you a voice message, I am seeing what time it best for RAD to be part of the call.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>

Sent: Tuesday, March 26, 2019 11:30 AM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: P-16-05X3

Hi folks –

Just thought I would check in with you on this.

Thanks again - Tom

From: Berger, Tom C.

Sent: Friday, March 22, 2019 2:12 PM

To: 'Bauer.jeff@Epa.gov' <Bauer.jeff@Epa.gov>; 'Schweer, Greg' <Schweer.Greg@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: P-16-05X3

Hi folks –

I hope you are doing well. Jeff – this is the PMN case that my colleague, Dr. Rhys Daniels, spoke with you about earlier this week.

The issue is development of data needed to amend the existing section 5(e) order for this substance to add an additional use, and EPA approval of protocols for same. Would the Agency be available for a short conference call on this on one of the following days?:

- March 27 (except 12-2 ET)
- April 2
- April 3
- April 4

This is becoming more urgent from a commercial standpoint.

Thanks much - Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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Message

From: Bauer, Jeff [Bauer.Jeff@epa.gov]
Sent: 3/29/2019 9:42:38 PM
To: Berger, Tom C. [Berger@khlaw.com]; Schweer, Greg [Schweer.Greg@epa.gov]
CC: Daniels, Rhys G. [daniels@khlaw.com]
Subject: RE: P-16-05X3

Tom,
I set the meeting up for Wednesday April 3, at 11 am. RAD has accepted the invitation for that time.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Bauer, Jeff
Sent: Tuesday, March 26, 2019 11:37 AM
To: 'Berger, Tom C.' <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

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Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Tuesday, March 26, 2019 11:30 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

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Thanks again - Tom

From: Berger, Tom C.
Sent: Friday, March 22, 2019 2:12 PM
To: 'Bauer.jeff@Epa.gov' <Bauer.jeff@Epa.gov>; 'Schweer, Greg' <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: P-16-05X3

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- March 27 (except 12-2 ET)
- April 2
- April 3
- April 4

This is becoming more urgent from a commercial standpoint.

Thanks much - Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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Message

From: Berger, Tom C. [Berger@khlaw.com]
Sent: 3/28/2019 6:52:56 PM
To: Bauer, Jeff [Bauer.Jeff@epa.gov]
CC: Schweer, Greg [Schweer.Greg@epa.gov]; Daniels, Rhys G. [daniels@khlaw.com]
Subject: RE: P-16-05X3

Hi Jeff –

Are we “on” for some time next Wednesday? If so I will circulate an MS Outlook invite with dial-in instructions.

Thanks again and best regards,
Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Tuesday, March 26, 2019 11:37 AM
To: Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Tom, I left you a voice message, I am seeing what time it best for RAD to be part of the call.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Tuesday, March 26, 2019 11:30 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

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Thanks again - Tom

From: Berger, Tom C.
Sent: Friday, March 22, 2019 2:12 PM

To: 'Bauer.jeff@Epa.gov' <Bauer.jeff@Epa.gov>; 'Schweer, Greg' <Schweer.Greg@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: P-16-05X3

Hi folks –

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- March 27 (except 12-2 ET)
- April 2
- April 3
- April 4

This is becoming more urgent from a commercial standpoint.

Thanks much - Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com

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Message

From: Hoffer, Danielle [hoffer.danielle@epa.gov]
Sent: 5/14/2020 6:16:54 PM
To: tlwill@ascendmaterials.com
CC: Scott J. Burya, Ph.D. [sburya@lawbc.com]; Schweer, Greg [Schweer.Greg@epa.gov]
Subject: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19
Attachments: Agreement to authorize transmittal of TSCA.docx

Dear Travis Willard,

Scott requested that I send this authorization form for transmitting CBI over email to you so I can send some of the draft reports for your cases (P-20-0078, P-20-0080-82). Below are more details about why we are requesting this:

In an effort to encourage social distancing and help reduce community spread of COVID-19, most EPA staff have been authorized to telework. With a majority of EPA staff now teleworking from remote sites, some minor changes to the normal TSCA section 5 review processes, including the TSCA section 5(a)(3) determination processes, are required. Specifically, the normal process by which section 5(a)(3)(C) determination documents, section 5(e) orders, and assessment reports are transmitted to submitters, because they contain information claimed as CBI, are hard copies submitted by the mail or courier services and via fax machines. These methods of delivery are not available from remote sites and therefore other means of transmitting this information must be utilized.



Given this extraordinary situation, and to avoid delay in addressing TSCA section 5 requirements, the Agency is offering an option to allowed affected persons to agree to allow EPA to transmit these materials via normal non-encrypted Outlook email. If you agree to this, the Agency will transmit these documents to you via email during the period in which a majority of EPA staff is teleworking. In the absence of this agreement EPA may need to extend the review period for your submission or issue a unilateral order under Section 5(e). Please note that EPA is not requiring companies to agree to transmission via email. Rather this communication explains the constraints we are acting under, and the delays that would result in the absence of email transmission. Companies are free to choose as appropriate.

Also, please note that agreeing to this process is a limited waiver of the TSCA CBI procedural protections, which generally restricts the transmission of CBI over a non-encrypted email system. That said, EPA's email system is compliant with all applicable Federal government information security provisions, including the Federal Information Security Management Act, and EPA's email systems meet the level of protection required for storing and transmitting CBI. Furthermore, your agreement will not constitute a waiver of substantive CBI protections, meaning that the information transmitted and claimed as confidential will only be disclosed consistent with TSCA, other applicable laws, and associated implementing regulations.

If you wish to grant EPA a limited waiver to transmit the materials via EPA's email system during the period in which a majority of EPA staff is teleworking, please have your authorized representative complete (e.g., add the case numbers[all four]), sign, and return the attached to Greg Schweer (Schweer.greg@epa.gov) as well as to any EPA staff who were cc'd on the email sent to you. If you have any questions about this communication or the described process, please contact Greg Schweer at (202) 564-8469 or the EPA Program Manager assigned to the case.

Best Regards,

Danielle Hoffer
Environmental Protection Specialist
U.S. Environmental Protection Agency
Office of Chemical Safety and Pollution Prevention
Office of Pollution Prevention and Toxics
Chemical Control Division
New Chemicals Management Branch
(202) 564-0556

 Please do not print this email unless absolutely necessary 

Agreement to authorize transmittal of TSCA Confidential Business Information (CBI) via Outlook email by designated Agency representatives during the period of EPA telework due to COVID-19

Documents concerning: PMN-XX-XXX

COMPANY authorizes EPA to transmit documents related to the above referenced TSCA submission, including information claimed as CBI, to **COMPANY** (or its technical contact listed on the PMN form) through EPA's Outlook email system. This authorization applies only during those periods where EPA staff working on PMN-XX-XXX are teleworking due to COVID-19 concerns and may be withdrawn at any time. Nothing in this authorization diminishes or otherwise limits **COMPANY'S** protections under TSCA to assert information as CBI, or otherwise authorizes the release of any information claimed as CBI without exhausting all provisions of TSCA protecting the release of such information. I have the authority to sign this on behalf of **COMPANY**

Signature of authorized person: _

Name of authorized person printed or typed: _

Title: _

Email address: _____

Telephone number: _

COMPANY _____

Message

From: Bauer, Jeff [Bauer.Jeff@epa.gov]
Sent: 3/26/2019 3:36:30 PM
To: Berger, Tom C. [Berger@khlaw.com]; Schweer, Greg [Schweer.Greg@epa.gov]
CC: Daniels, Rhys G. [daniels@khlaw.com]
Subject: RE: P-16-05X3

Tom, I left you a voice message, I am seeing what time it best for RAD to be part of the call.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Tuesday, March 26, 2019 11:30 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: P-16-05X3

Hi folks –

Just thought I would check in with you on this.

Thanks again - Tom

From: Berger, Tom C.
Sent: Friday, March 22, 2019 2:12 PM
To: 'Bauer.jeff@Epa.gov' <Bauer.jeff@Epa.gov>; 'Schweer, Greg' <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: P-16-05X3

Hi folks –

I hope you are doing well. Jeff – this is the PMN case that my colleague, Dr. Rhys Daniels, spoke with you about earlier this week.

The issue is development of data needed to amend the existing section 5(e) order for this substance to add an additional use, and EPA approval of protocols for same. Would the Agency be available for a short conference call on this on one of the following days?:

- March 27 (except 12-2 ET)
- April 2

- April 3
- April 4

This is becoming more urgent from a commercial standpoint.

Thanks much - Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com

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Message

From: Berger, Tom C. [Berger@khlaw.com]
Sent: 5/13/2020 5:34:00 PM
To: Bauer, Jeff [Bauer.Jeff@epa.gov]
CC: Price, Amanda [price@khlaw.com]; Schweer, Greg [Schweer.Greg@epa.gov]; Daniels, Rhys G. [daniels@khlaw.com]
Subject: RE: **Ex. 4 CBI**

Jeff – yes – thanks. I am checking with the submitter to see if that date/time works for them.

Thanks again - Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, May 13, 2020 1:32 PM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom,

I sent a meeting request to you three for May 27th at 2 p.m. to give a status update as requested.

Thanks

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Wednesday, May 13, 2020 12:53 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just seeing if it makes sense to set up a conference call in a week or two.

Thanks much again - Tom

From: Berger, Tom C.
Sent: Friday, May 8, 2020 11:14 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: P-16-05X3

Jeff/Greg – thanks again.

Can/should we schedule a conference call with the submitter in a week or two?

Happy Friday!

Tom

From: Berger, Tom C.

Sent: Thursday, May 7, 2020 4:17 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: Re: **Ex. 4 CBI**

Jeff - thanks much.

Tom

On May 7, 2020, at 4:03 PM, Bauer, Jeff <Bauer.Jeff@epa.gov> wrote:

Tom, I hope you hanging in there as well, I have an email out to see if I can get a status update on the Assessor and to address you questions sent into CDX for a meeting.

Jeff

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>

Sent: Thursday, May 07, 2020 1:57 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff – Just touching base as the submitter has requested a status update.

Thanks again - Tom

From: Berger, Tom C.
Sent: Tuesday, May 5, 2020 11:56 AM
To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; 'Schweer, Greg' <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff – Just checking in on this – thanks - Tom

From: Berger, Tom C.
Sent: Wednesday, April 29, 2020 11:12 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I just thought I would check in on this and see if the Agency needs any additional information.

Thanks again and best regards,
Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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From: Berger, Tom C.
Sent: Thursday, April 23, 2020 7:13 PM
To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Jeff - thanks much.

Your recent voicemail and follow-up email indicated that the EPA Chemist has evaluated the study" on **Ex. 4 CBI** but that the reviewer did have a few questions and comments:

Ex. 4 CBI

Ex. 4 CBI

Ex. 4 CBI

To specifically answer the Chemist's questions:

Ex. 4 CBI

Ex. 4 CBI

* * *

We trust that you find this information useful in resolved all outstanding issues. As always, if you have any questions please do not hesitate to contact us.

Best regards,
Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Tuesday, April 21, 2020 5:17 PM
To: Daniels, Rhys G. <daniels@khlaw.com>; Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: **Ex. 4 CBI**

I am moving forward with the review based on the information I have on the two studies, I wanted to share with you her comments on the test. **Ex. 4 CBI**

Ex. 4 CBI RAD has the information and I am trying to get them to do the risk assessment based on **Ex. 4 CBI**

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

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1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Daniels, Rhys G. <daniels@khlaw.com>
Sent: Tuesday, April 21, 2020 4:58 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: **Ex. 4 CBI**

Jeff,

As always, we hope that all is well.

Per your recent voicemail and follow-up email concerning the **Ex. 4 CBI** case, we understand that the chemist has two questions concerning **Ex. 4 CBI**

Ex. 4 CBI

Ex. 4 CBI

Thanks in advance for your response.

Rhys G. Daniels, Ph.D.

Staff Scientist

tel: +1 202.434.4270 | fax: +1 202.434.4646 | daniels@khlaw.com

1001 G Street NW, Suite 500 West | Washington, DC 20001



From: Bauer, Jeff <Bauer.Jeff@epa.gov>

Sent: Thursday, April 16, 2020 1:02 PM

To: Berger, Tom C. <Berger@khlaw.com>

Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>

Subject: RE: Ex. 4 CBI

Tom,

The chemist sent me a memo Ex. 4 CBI and they had two questions, I called and left you a message today Ex. 4 CBI I sent RAD a request last week to update the HH assessment Ex. 4 CBI as in my April 4, 2020 email to you. I have two emails into RAD on this case and will try an update you again in a week or so. I requested RAD set up a date with me to have a meeting to discuss how to proceed with this PMN.

Thanks

Jeff

Jeff Bauer - Program Manager

United States Environmental Protection Agency (USEPA)

Office of Pollution Prevention and Toxics (OPPT)

New Chemicals Program (7405M)

<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M

1201 Constitution Ave., NW

Washington, DC 20004

Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>

Sent: Thursday, April 16, 2020 12:28 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope that all is well.

Just checking in re status update. A non-CBI-containing email from you would probably be the best (if needed at some later time we can use EPA's new CBI via email authorization form if the submitter agrees).

Thanks again – Tom

From: Berger, Tom C.

Sent: Wednesday, April 8, 2020 11:06 AM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Jeff – thanks much for the update. Hope you and all at EPA are staying safe.

Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>

Sent: Wednesday, April 8, 2020 11:03 AM

To: Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Tom,

Ex. 4 CBI

I will follow up with you next wed with a status update.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

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1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Wednesday, April 08, 2020 10:48 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>
Subject: RE: Ex. 4 CBI

Hi Greg –

I was just going through my to-do list and thought I would circle back on these two cases. I hope everyone is hanging in there.

Thanks again – Tom

From: Berger, Tom C.
Sent: Monday, March 30, 2020 3:46 PM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>
Subject: RE: Ex. 4 CBI

Greg / all – completely understood – thank you so much.

Tom

From: Schweer, Greg <Schweer.Greg@epa.gov>
Sent: Monday, March 30, 2020 3:42 PM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>
Subject: RE: Ex. 4 CBI

Hi Tom.

I am not ignoring you. I did check with Jeff Bauer early last week on this case. He filled me in on the requests he had made of RAD to review submitted test data and your request for a meeting. However, believe it or not, we have been having issues reliably being able to access our CBI-secure LAN. This hampers our ability to efficiently complete work. I will check on the status of your case as soon as I can.

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Monday, March 30, 2020 11:51 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: Ex. 4 CBI

Hi Greg –

Hope all is well.

Just thought I would check in with you on the Ex. 4 CBI LVEA (Lauren Davis) and Ex. 4 CBI with Jeff Bauer.

Thanks all always - Tom

From: Berger, Tom C.
Sent: Tuesday, March 24, 2020 11:12 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Greg – thanks so much as always. I also have an LVE with Lauren Davis **Ex. 4 CBI** held up in the process. Lauren has been responsive but the case has stalled (again, however, I understand the challenges you are facing).

These are my two “priority” cases.

Tom

From: Schweer, Greg <Schweer.Greg@epa.gov>
Sent: Tuesday, March 24, 2020 11:07 AM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: Re: **Ex. 4 CBI**

Tom,

Yes, things are a bit crazy. I will check into the case status today or tomorrow.

Sent from my iPhone

On Mar 24, 2020, at 10:48 AM, Berger, Tom C. <Berger@khlaw.com> wrote:

Hi Greg –

Obviously things are crazy and I don't want to push Jeff too hard but no response from Jeff on this case for a month.

Hang in there....

Tom

From: Berger, Tom C.
Sent: Monday, March 23, 2020 6:22 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies – just want to make sure you are getting these emails. Understand if there are delays.

Tom

From: Berger, Tom C.
Sent: Thursday, March 19, 2020 5:22 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff – checking in again – thanks - Tom

From: Berger, Tom C.
Sent: Monday, March 16, 2020 1:40 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I know things are crazy but checking in again – thanks - Tom

From: Berger, Tom C.
Sent: Wednesday, March 11, 2020 3:43 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Checking in again - thanks

From: Berger, Tom C.
Sent: Friday, March 6, 2020 1:33 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

The submitter is quite anxious – can we touch base next week?

Thanks much - Tom

From: Berger, Tom C.
Sent: Tuesday, February 25, 2020 9:08 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just checking in on this – thanks - Tom

From: Berger, Tom C.
Sent: Thursday, February 20, 2020 12:18 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope that all is well.

Per our discussions, the submitter has modified the questions to focus on toxicity/risk issues and submitted them via CDX yesterday. Can we start looking at conference call dates the week of March 9?

Thanks and best regards,
Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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From: Berger, Tom C.
Sent: Wednesday, January 29, 2020 11:41 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies we keep playing phone tag – can we discuss how to convert the below questions into questions that would be acceptable to RAD so we can schedule a call with you and RAD? Your voicemail suggested the below are more legal/regulatory than risk-based questions. We still need the below questions answered – perhaps we tee up the more scientific ones for RAD then have the call to address both types of questions. The submitter is under growing commercial pressure.

Thanks much again - Tom

From: Berger, Tom C.
Sent: Monday, January 20, 2020 3:50 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies that we could not connect last week. Let's try to touch base tomorrow (Tuesday) if possible to discuss how to move this forward.

Thanks again – Tom

Thomas C. Berger

Partner

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From: Berger, Tom C.

Sent: Monday, January 13, 2020 2:50 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Importance: High

Hi Jeff –

Following is the list of questions we are considering submitting through CDX. Please let me know if these look ok.

Thanks again and best regards,
Tom

* * *

*(1) Based on review of the submitted physical-chemical properties test data, does EPA now agree that use **Ex. 4 CBI** as described in the PMN poses no unreasonable risk of injury and so plans to revoke the consent order?*

(2) If so, what is the process for revoking the current consent order? Does the submitter now need to request that EPA revoke the order, or will EPA itself initiate revocation? What is the expected timing for revocation? How would EPA communicate such revocation?

(3) How would revocation of the consent order impact the final SNUR for the subject substance?

(4) Would a SNUN be a more expedient approach?

* * *

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, January 8, 2020 8:56 AM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom, I am expecting information from the engineer today or tomorrow on the **Ex. 4 CBI** test, I left you a message. There is a new procedure for us to set up meeting with RAD. I am to have the submitter send in a list of questions for RAD, they will assign someone up there as a Lead person who has two weeks and will set a date for when we can have a meeting. This may be our best route to other than just me bugging them to get things done. There were a series of emails on this case last week but now everyone is back from the holidays I am trying to get this case moving again.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

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Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Tuesday, January 07, 2020 4:16 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope you had a great holiday! The client was wondering if we could have a conference call on this, this week or next. Please advise.

Thanks much – Tom

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From: Berger, Tom C.
Sent: Tuesday, December 10, 2019 2:10 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just checking back in – thanks - Tom

From: Berger, Tom C.
Sent: Thursday, December 5, 2019 9:46 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

When we spoke before Thanksgiving (I hope you had a great one!) you indicated that the reports were being reviewed and that I should reach out to you in early December.

Is there any update?

Thanks much and best regards – Tom

Thomas C. Berger
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From: Berger, Tom C.
Sent: Monday, November 18, 2019 1:17 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

The PMN submitter asked me to reach out to you to see if we can schedule a conference call (including EPA, K&H, and the submitter) on this case re status and pathforward.

Thanks - Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>

Sent: Friday, March 29, 2019 5:43 PM

To: Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Tom,

I set the meeting up for Wednesday April 3, at 11 am. RAD has accepted the invitation for that time.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

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Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Bauer, Jeff

Sent: Tuesday, March 26, 2019 11:37 AM

To: 'Berger, Tom C.' <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Tom, I left you a voice message, I am seeing what time it best for RAD to be part of the call.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

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1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Tuesday, March 26, 2019 11:30 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi folks –

Just thought I would check in with you on this.

Thanks again - Tom

From: Berger, Tom C.
Sent: Friday, March 22, 2019 2:12 PM
To: 'Bauer.jeff@Epa.gov' <Bauer.jeff@Epa.gov>; 'Schweer, Greg' <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: **Ex. 4 CBI**

Hi folks –

I hope you are doing well. Jeff – this is the PMN case that my colleague, Dr. Rhys Daniels, spoke with you about earlier this week.

The issue is development of data needed to amend the existing section 5(e) order for this substance to add an additional use, and EPA approval of protocols for same. Would the Agency be available for a short conference call on this on one of the following days?:

- March 27 (except 12-2 ET)
- April 2
- April 3
- April 4

This is becoming more urgent from a commercial standpoint.

Thanks much - Tom

Thomas C. Berger
Partner
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Message

From: Berger, Tom C. [Berger@khlaw.com]
Sent: 3/26/2019 3:29:53 PM
To: Bauer, Jeff [Bauer.Jeff@epa.gov]; Schweer, Greg [Schweer.Greg@epa.gov]
CC: Daniels, Rhys G. [daniels@khlaw.com]
Subject: RE: P-16-05X3

Hi folks –

Just thought I would check in with you on this.

Thanks again - Tom

From: Berger, Tom C.
Sent: Friday, March 22, 2019 2:12 PM
To: 'Bauer.jeff@Epa.gov' <Bauer.jeff@Epa.gov>; 'Schweer, Greg' <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: P-16-05X3

Hi folks –

I hope you are doing well. Jeff – this is the PMN case that my colleague, Dr. Rhys Daniels, spoke with you about earlier this week.

The issue is development of data needed to amend the existing section 5(e) order for this substance to add an additional use, and EPA approval of protocols for same. Would the Agency be available for a short conference call on this on one of the following days?:

- March 27 (except 12-2 ET)
- April 2
- April 3
- April 4

This is becoming more urgent from a commercial standpoint.

Thanks much - Tom

Thomas C. Berger
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Message

From: Bauer, Jeff [Bauer.Jeff@epa.gov]
Sent: 5/13/2020 5:32:17 PM
To: Berger, Tom C. [Berger@khlaw.com]
CC: Price, Amanda [price@khlaw.com]; Schweer, Greg [Schweer.Greg@epa.gov]; Daniels, Rhys G. [daniels@khlaw.com]
Subject: RE: **Ex. 4 CBI**

Tom,

I sent a meeting request to you three for May 27th at 2 p.m. to give a status update as requested.

Thanks

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

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Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Wednesday, May 13, 2020 12:53 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just seeing if it makes sense to set up a conference call in a week or two.

Thanks much again - Tom

From: Berger, Tom C.
Sent: Friday, May 8, 2020 11:14 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Jeff/Greg – thanks again.

Can/should we schedule a conference call with the submitter in a week or two?

Happy Friday!

Tom

From: Berger, Tom C.
Sent: Thursday, May 7, 2020 4:17 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: Re: **Ex. 4 CBI**

Jeff - thanks much.

Tom

On May 7, 2020, at 4:03 PM, Bauer, Jeff <Bauer.Jeff@epa.gov> wrote:

Tom, I hope you hanging in there as well, I have an email out to see if I can get a status update on the Assessor and to address your questions sent into CDX for a meeting.

Jeff

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

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From: Berger, Tom C. <Berger@khlaw.com>
Sent: Thursday, May 07, 2020 1:57 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff – Just touching base as the submitter has requested a status update.

Thanks again - Tom

From: Berger, Tom C.
Sent: Tuesday, May 5, 2020 11:56 AM
To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; 'Schweer, Greg' <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff – Just checking in on this – thanks - Tom

From: Berger, Tom C.
Sent: Wednesday, April 29, 2020 11:12 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I just thought I would check in on this and see if the Agency needs any additional information.

Thanks again and best regards,
Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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From: Berger, Tom C.
Sent: Thursday, April 23, 2020 7:13 PM
To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Jeff - thanks much.

Your recent voicemail and follow-up email indicated that the EPA Chemist has evaluated the study" on **Ex. 4 CBI** but that the reviewer did have a few questions and comments:

Ex. 4 CBI

Ex. 4 CBI

To specifically answer the Chemist's questions:

Ex. 4 CBI

Ex. 4 CBI

* * *

We trust that you find this information useful in resolved all outstanding issues. As always, if you have any questions please do not hesitate to contact us.

Best regards,
Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Tuesday, April 21, 2020 5:17 PM
To: Daniels, Rhys G. <daniels@khlaw.com>; Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: **Ex. 4 CBI**

I am moving forward with the review based on the information I have on the two studies, I wanted to share with you her comments on the test. **Ex. 4 CBI**

Ex. 4 CBI RAD has the information and I am trying to get them to do the risk assessment based on **Ex. 4 CBI**

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

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Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Daniels, Rhys G. <daniels@khlaw.com>
Sent: Tuesday, April 21, 2020 4:58 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: **Ex. 4 CBI**

Jeff,

As always, we hope that all is well.

Per your recent voicemail and follow-up email concerning the **Ex. 4 CBI** case, we understand that the chemist has two questions concerning **Ex. 4 CBI**

Ex. 4 CBI

Thanks in advance for your response.

Rhys G. Daniels, Ph.D.
Staff Scientist
tel: +1 202.434.4270 | fax: +1 202.434.4646 | daniels@khlaw.com

1001 G Street NW, Suite 500 West | Washington, DC 20001

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Thursday, April 16, 2020 1:02 PM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: [Ex. 4 CBI]

Tom,

The chemist sent me a memo [Ex. 4 CBI] and they had two questions, I called and left you a message today [Ex. 4 CBI] I sent RAD a request last week to update the HH assessment [Ex. 4 CBI] as in my April 4, 2020 email to you. I have two emails into RAD on this case and will try an update you again in a week or so. I requested RAD set up a date with me to have a meeting to discuss how to proceed with this PMN.

Thanks
Jeff

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

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Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Thursday, April 16, 2020 12:28 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: [Ex. 4 CBI]

Hi Jeff –

I hope that all is well.

Just checking in re status update. A non-CBI-containing email from you would probably be the best (if needed at some later time we can use EPA's new CBI via email authorization form if the submitter agrees).

Thanks again – Tom

From: Berger, Tom C.
Sent: Wednesday, April 8, 2020 11:06 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Jeff – thanks much for the update. Hope you and all at EPA are staying safe.

Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, April 8, 2020 11:03 AM
To: Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom,

Ex. 4 CBI

I will follow up with you next wed with a status update.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

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1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Wednesday, April 08, 2020 10:48 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Greg –

I was just going through my to-do list and thought I would circle back on these two cases. I hope everyone is hanging in there.

Thanks again – Tom

From: Berger, Tom C.

Sent: Monday, March 30, 2020 3:46 PM

To: Schweer, Greg <Schweer.Greg@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>

Subject: RE: Ex. 4 CBI

Greg / all – completely understood – thank you so much.

Tom

From: Schweer, Greg <Schweer.Greg@epa.gov>

Sent: Monday, March 30, 2020 3:42 PM

To: Berger, Tom C. <Berger@khlaw.com>

Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>

Subject: RE: Ex. 4 CBI

Hi Tom.

I am not ignoring you. I did check with Jeff Bauer early last week on this case. He filled me in on the requests he had made of RAD to review submitted test data and your request for a meeting. However, believe it or not, we have been having issues reliably being able to access our CBI-secure LAN. This hampers our ability to efficiently complete work. I will check on the status of your case as soon as I can.

From: Berger, Tom C. <Berger@khlaw.com>

Sent: Monday, March 30, 2020 11:51 AM

To: Schweer, Greg <Schweer.Greg@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: Ex. 4 CBI

Hi Greg –

Hope all is well.

Just thought I would check in with you on the Ex. 4 CBI LVEA (Lauren Davis) and Ex. 4 CBI Ex. 4 CBI with Jeff Bauer.

Thanks all always - Tom

From: Berger, Tom C.

Sent: Tuesday, March 24, 2020 11:12 AM

To: Schweer, Greg <Schweer.Greg@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: Ex. 4 CBI

Greg – thanks so much as always. I also have an LVE with Lauren Davis

Ex. 4 CBI

Ex. 4 CBI held up in the process. Lauren has been responsive but the case has stalled (again, however, I understand the challenges you are facing).

These are my two “priority” cases.

Tom

From: Schweer, Greg <Schweer.Greg@epa.gov>

Sent: Tuesday, March 24, 2020 11:07 AM

To: Berger, Tom C. <Berger@khlaw.com>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: Re: Ex. 4 CBI

Tom,

Yes, things are a bit crazy. I will check into the case status today or tomorrow.

Sent from my iPhone

On Mar 24, 2020, at 10:48 AM, Berger, Tom C. <Berger@khlaw.com> wrote:

Hi Greg –

Obviously things are crazy and I don’t want to push Jeff too hard but no response from Jeff on this case for a month.

Hang in there....

Tom

From: Berger, Tom C.

Sent: Monday, March 23, 2020 6:22 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: Ex. 4 CBI

Hi Jeff –

Apologies – just want to make sure you are getting these emails. Understand if there are delays.

Tom

From: Berger, Tom C.

Sent: Thursday, March 19, 2020 5:22 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: Ex. 4 CBI

Hi Jeff – checking in again – thanks - Tom

From: Berger, Tom C.
Sent: Monday, March 16, 2020 1:40 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I know things are crazy but checking in again – thanks - Tom

From: Berger, Tom C.
Sent: Wednesday, March 11, 2020 3:43 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Checking in again - thanks

From: Berger, Tom C.
Sent: Friday, March 6, 2020 1:33 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

The submitter is quite anxious – can we touch base next week?

Thanks much - Tom

From: Berger, Tom C.
Sent: Tuesday, February 25, 2020 9:08 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just checking in on this – thanks - Tom

From: Berger, Tom C.
Sent: Thursday, February 20, 2020 12:18 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope that all is well.

Per our discussions, the submitter has modified the questions to focus on toxicity/risk issues and submitted them via CDX yesterday. Can we start looking at conference call dates the week of March 9?

Thanks and best regards,
Tom

Thomas C. Berger
Partner
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From: Berger, Tom C.
Sent: Wednesday, January 29, 2020 11:41 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies we keep playing phone tag – can we discuss how to convert the below questions into questions that would be acceptable to RAD so we can schedule a call with you and RAD? Your voicemail suggested the below are more legal/regulatory than risk-based questions. We still need the below questions answered – perhaps we tee up the more scientific ones for RAD then have the call to address both types of questions. The submitter is under growing commercial pressure.

Thanks much again - Tom

From: Berger, Tom C.
Sent: Monday, January 20, 2020 3:50 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies that we could not connect last week. Let's try to touch base tomorrow (Tuesday) if possible to discuss how to move this forward.

Thanks again – Tom

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From: Berger, Tom C.
Sent: Monday, January 13, 2020 2:50 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**
Importance: High

Hi Jeff –

Following is the list of questions we are considering submitting through CDX. Please let me know if these look ok.

Thanks again and best regards,
Tom

* * *

*(1) Based on review of the submitted physical-chemical properties test data, does EPA now agree that use of **Ex. 4 CBI** as described in the PMN poses no unreasonable risk of injury and so plans to revoke the consent order?*

(2) If so, what is the process for revoking the current consent order? Does the submitter now need to request that EPA revoke the order, or will EPA itself initiate revocation? What is the expected timing for revocation? How would EPA communicate such revocation?

(3) How would revocation of the consent order impact the final SNUR for the subject substance?

(4) Would a SNUN be a more expedient approach?

* * *

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, January 8, 2020 8:56 AM
To: Berger, Tom C. <Berger@khlaw.com>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Tom, I am expecting information from the engineer today or tomorrow on the **Ex. 4 CBI** test. I left you a message. There is a new procedure for us to set up meeting with RAD. I am to have the submitter send in a list of questions for RAD, they will assign someone up there as a Lead person who has two weeks and will set a date for when we can have a meeting. This may be our best route to other than just me bugging them to get things done. There were a series of emails on this case last week but now everyone is back from the holidays I am trying to get this case moving again.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

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1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>

Sent: Tuesday, January 07, 2020 4:16 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope you had a great holiday! The client was wondering if we could have a conference call on this, this week or next. Please advise.

Thanks much – Tom

Thomas C. Berger
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tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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From: Berger, Tom C.
Sent: Tuesday, December 10, 2019 2:10 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just checking back in – thanks - Tom

From: Berger, Tom C.
Sent: Thursday, December 5, 2019 9:46 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

When we spoke before Thanksgiving (I hope you had a great one!) you indicated that the reports were being reviewed and that I should reach out to you in early December.

Is there any update?

Thanks much and best regards – Tom

Thomas C. Berger
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From: Berger, Tom C.
Sent: Monday, November 18, 2019 1:17 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

The PMN submitter asked me to reach out to you to see if we can schedule a conference call (including EPA, K&H, and the submitter) on this case re status and pathforward.

Thanks - Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Friday, March 29, 2019 5:43 PM
To: Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom,
I set the meeting up for Wednesday April 3, at 11 am. RAD has accepted the invitation for that time.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Bauer, Jeff
Sent: Tuesday, March 26, 2019 11:37 AM
To: 'Berger, Tom C.' <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom, I left you a voice message, I am seeing what time it best for RAD to be part of the call.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

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1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Tuesday, March 26, 2019 11:30 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi folks –

Just thought I would check in with you on this.

Thanks again - Tom

From: Berger, Tom C.
Sent: Friday, March 22, 2019 2:12 PM
To: 'Bauer.jeff@Epa.gov' <Bauer.jeff@Epa.gov>; 'Schweer, Greg' <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: **Ex. 4 CBI**

Hi folks –

I hope you are doing well. Jeff – this is the PMN case that my colleague, Dr. Rhys Daniels, spoke with you about earlier this week.

The issue is development of data needed to amend the existing section 5(e) order for this substance to add an additional use, and EPA approval of protocols for same. Would the Agency be available for a short conference call on this on one of the following days?:

- March 27 (except 12-2 ET)
- April 2
- April 3
- April 4

This is becoming more urgent from a commercial standpoint.

Thanks much - Tom

Thomas C. Berger
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tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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Message

From: Berger, Tom C. [Berger@khlaw.com]
Sent: 3/22/2019 6:12:15 PM
To: Bauer, Jeff [Bauer.Jeff@epa.gov]; Schweer, Greg [Schweer.Greg@epa.gov]
CC: Daniels, Rhys G. [daniels@khlaw.com]
Subject: P-16-05X3

Hi folks –

I hope you are doing well. Jeff – this is the PMN case that my colleague, Dr. Rhys Daniels, spoke with you about earlier this week.

The issue is development of data needed to amend the existing section 5(e) order for this substance to add an additional use, and EPA approval of protocols for same. Would the Agency be available for a short conference call on this on one of the following days?:

- March 27 (except 12-2 ET)
- April 2
- April 3
- April 4

This is becoming more urgent from a commercial standpoint.

Thanks much - Tom

Thomas C. Berger
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Message

From: Bauer, Jeff [Bauer.Jeff@epa.gov]
Sent: 5/13/2020 5:09:07 PM
To: Berger, Tom C. [Berger@khlaw.com]
CC: Price, Amanda [price@khlaw.com]; Schweer, Greg [Schweer.Greg@epa.gov]; Daniels, Rhys G. [daniels@khlaw.com]
Subject: RE: **Ex. 4 CBI**

Tom,

I am hoping to have something to discuss with you soon. I had a conversation with someone in RAD on Tuesday night and explained what I am looking for **Ex. 4 CBI**

Ex. 4 CBI
Ex. 4 CBI I will follow up with him again next week.

I am going to follow up with you on the phone

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

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1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Wednesday, May 13, 2020 12:53 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just seeing if it makes sense to set up a conference call in a week or two.

Thanks much again - Tom

From: Berger, Tom C.
Sent: Friday, May 8, 2020 11:14 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Jeff/Greg – thanks again.

Can/should we schedule a conference call with the submitter in a week or two?

Happy Friday!

Tom

From: Berger, Tom C.

Sent: Thursday, May 7, 2020 4:17 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: Re: **Ex. 4 CBI**

Jeff - thanks much.

Tom

On May 7, 2020, at 4:03 PM, Bauer, Jeff <Bauer.Jeff@epa.gov> wrote:

Tom, I hope you hanging in there as well, I have an email out to see if I can get a status update on the Assessor and to address your questions sent into CDX for a meeting.

Jeff

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

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Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>

Sent: Thursday, May 07, 2020 1:57 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff – Just touching base as the submitter has requested a status update.

Thanks again - Tom

From: Berger, Tom C.

Sent: Tuesday, May 5, 2020 11:56 AM

To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; 'Schweer, Greg' <Schweer.Greg@epa.gov>; Daniels, Rhys G.

<daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff – Just checking in on this – thanks - Tom

From: Berger, Tom C.

Sent: Wednesday, April 29, 2020 11:12 AM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I just thought I would check in on this and see if the Agency needs any additional information.

Thanks again and best regards,
Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com

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From: Berger, Tom C.

Sent: Thursday, April 23, 2020 7:13 PM

To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Jeff - thanks much.

Your recent voicemail and follow-up email indicated that the EPA Chemist has evaluated the study on **Ex. 4 CBI** but that the reviewer did have a few questions and comments:

Ex. 4 CBI

Ex. 4 CBI

Ex. 4 CBI

To specifically answer the Chemist's questions:

Ex. 4 CBI

Ex. 4 CBI

* * *

We trust that you find this information useful in resolved all outstanding issues. As always, if you have any questions please do not hesitate to contact us.

Best regards,
Tom

Thomas C. Berger
Partner
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From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Tuesday, April 21, 2020 5:17 PM
To: Daniels, Rhys G. <daniels@khlaw.com>; Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: **Ex. 4 CBI**

I am moving forward with the review based on the information I have on the two studies, I wanted to share with you her comments on the test. **Ex. 4 CBI**

Ex. 4 CBI RAD has the information and I am trying to get them to do the risk assessment based on **Ex. 4 CBI**

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

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Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Daniels, Rhys G. <daniels@khlaw.com>
Sent: Tuesday, April 21, 2020 4:58 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: **Ex. 4 CBI**

Jeff,

As always, we hope that all is well.

Per your recent voicemail and follow-up email concerning the **Ex. 4 CBI** case, we understand that the chemist has two questions **Ex. 4 CBI**

Ex. 4 CBI

Thanks in advance for your response.

Rhys G. Daniels, Ph.D.

Staff Scientist

tel: +1 202.434.4270 | fax: +1 202.434.4646 | daniels@khlaw.com

1001 G Street NW, Suite 500 West | Washington, DC 20001



From: Bauer, Jeff <Bauer.Jeff@epa.gov>

Sent: Thursday, April 16, 2020 1:02 PM

To: Berger, Tom C. <Berger@khlaw.com>

Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>

Subject: RE: **Ex. 4 CBI**

Tom,

The chemist sent me a memo **Ex. 4 CBI** and they had two questions, I called and left you a message today **Ex. 4 CBI**. I sent RAD a request last week to update the HH assessment **Ex. 4 CBI** as in my April 4, 2020 email to you. I have two emails into RAD on this case and will try an update you again in a week or so. I requested RAD set up a date with me to have a meeting to discuss how to proceed with this PMN.

Thanks

Jeff

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>

Sent: Thursday, April 16, 2020 12:28 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope that all is well.

Just checking in re status update. A non-CBI-containing email from you would probably be the best (if needed at some later time we can use EPA's new CBI via email authorization form if the submitter agrees).

Thanks again – Tom

From: Berger, Tom C.
Sent: Wednesday, April 8, 2020 11:06 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Jeff – thanks much for the update. Hope you and all at EPA are staying safe.

Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, April 8, 2020 11:03 AM
To: Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom,

Ex. 4 CBI

I will follow up with you next wed with a status update.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
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Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Wednesday, April 08, 2020 10:48 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda

<price@khlaw.com>

Subject: RE: Ex. 4 CBI

Hi Greg –

I was just going through my to-do list and thought I would circle back on these two cases. I hope everyone is hanging in there.

Thanks again – Tom

From: Berger, Tom C.

Sent: Monday, March 30, 2020 3:46 PM

To: Schweer, Greg <Schweer.Greg@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>

Subject: RE: Ex. 4 CBI

Greg / all – completely understood – thank you so much.

Tom

From: Schweer, Greg <Schweer.Greg@epa.gov>

Sent: Monday, March 30, 2020 3:42 PM

To: Berger, Tom C. <Berger@khlaw.com>

Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>

Subject: RE: Ex. 4 CBI

Hi Tom.

I am not ignoring you. I did check with Jeff Bauer early last week on this case. He filled me in on the requests he had made of RAD to review submitted test data and your request for a meeting. However, believe it or not, we have been having issues reliably being able to access our CBI-secure LAN. This hampers our ability to efficiently complete work. I will check on the status of your case as soon as I can.

From: Berger, Tom C. <Berger@khlaw.com>

Sent: Monday, March 30, 2020 11:51 AM

To: Schweer, Greg <Schweer.Greg@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: Ex. 4 CBI

Hi Greg –

Hope all is well.

Just thought I would check in with you on the Ex. 4 CBI LVEA (Lauren Davis) and Ex. 4 CBI Ex. 4 CBI with Jeff Bauer.

Thanks all always - Tom

From: Berger, Tom C.

Sent: Tuesday, March 24, 2020 11:12 AM

To: Schweer, Greg <Schweer.Greg@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Greg – thanks so much as always. I also have an LVE with Lauren Davis: **Ex. 4 CBI**

Ex. 4 CBI held up in the process. Lauren has been responsive but the case has stalled (again, however, I understand the challenges you are facing).

These are my two “priority” cases.

Tom

From: Schweer, Greg <Schweer.Greg@epa.gov>

Sent: Tuesday, March 24, 2020 11:07 AM

To: Berger, Tom C. <Berger@khlaw.com>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: Re: **Ex. 4 CBI**

Tom,

Yes, things are a bit crazy. I will check into the case status today or tomorrow.

Sent from my iPhone

On Mar 24, 2020, at 10:48 AM, Berger, Tom C. <Berger@khlaw.com> wrote:

Hi Greg –

Obviously things are crazy and I don't want to push Jeff too hard but no response from Jeff on this case for a month.

Hang in there....

Tom

From: Berger, Tom C.

Sent: Monday, March 23, 2020 6:22 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies – just want to make sure you are getting these emails. Understand if there are delays.

Tom

From: Berger, Tom C.

Sent: Thursday, March 19, 2020 5:22 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: Ex. 4 CBI

Hi Jeff – checking in again – thanks - Tom

From: Berger, Tom C.

Sent: Monday, March 16, 2020 1:40 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: Ex. 4 CBI

Hi Jeff –

I know things are crazy but checking in again – thanks - Tom

From: Berger, Tom C.

Sent: Wednesday, March 11, 2020 3:43 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: Ex. 4 CBI

Hi Jeff –

Checking in again - thanks

From: Berger, Tom C.

Sent: Friday, March 6, 2020 1:33 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: Ex. 4 CBI

Hi Jeff –

The submitter is quite anxious – can we touch base next week?

Thanks much - Tom

From: Berger, Tom C.

Sent: Tuesday, February 25, 2020 9:08 AM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: Ex. 4 CBI

Hi Jeff –

Just checking in on this – thanks - Tom

From: Berger, Tom C.

Sent: Thursday, February 20, 2020 12:18 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: Ex. 4 CBI

Hi Jeff –

I hope that all is well.

Per our discussions, the submitter has modified the questions to focus on toxicity/risk issues and submitted them via CDX yesterday. Can we start looking at conference call dates the week of March 9?

Thanks and best regards,
Tom

Thomas C. Berger
Partner
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From: Berger, Tom C.
Sent: Wednesday, January 29, 2020 11:41 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies we keep playing phone tag – can we discuss how to convert the below questions into questions that would be acceptable to RAD so we can schedule a call with you and RAD? Your voicemail suggested the below are more legal/regulatory than risk-based questions. We still need the below questions answered – perhaps we tee up the more scientific ones for RAD then have the call to address both types of questions. The submitter is under growing commercial pressure.

Thanks much again - Tom

From: Berger, Tom C.
Sent: Monday, January 20, 2020 3:50 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies that we could not connect last week. Let's try to touch base tomorrow (Tuesday) if possible to discuss how to move this forward.

Thanks again – Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com

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From: Berger, Tom C.

Sent: Monday, January 13, 2020 2:50 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: Ex. 4 CBI

Importance: High

Hi Jeff –

Following is the list of questions we are considering submitting through CDX. Please let me know if these look ok.

Thanks again and best regards,
Tom

* * *

(1) Based on review of the submitted physical-chemical properties test data, does EPA now agree that use Ex. 4 CBI as described in the PMN poses no unreasonable risk of injury and so plans to revoke the consent order?

(2) If so, what is the process for revoking the current consent order? Does the submitter now need to request that EPA revoke the order, or will EPA itself initiate revocation? What is the expected timing for revocation? How would EPA communicate such revocation?

(3) How would revocation of the consent order impact the final SNUR for the subject substance?

(4) Would a SNUN be a more expedient approach?

* * *

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, January 8, 2020 8:56 AM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom, I am expecting information from the engineer today or tomorrow on the **Ex. 4 CBI** test, I left you a message. There is a new procedure for us to set up meeting with RAD. I am to have the submitter send in a list of questions for RAD, they will assign someone up there as a Lead person who has two weeks and will set a date for when we can have a meeting. This may be our best route to other than just me bugging them to get things done. There were a series of emails on this case last week but now everyone is back from the holidays I am trying to get this case moving again.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

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1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Tuesday, January 07, 2020 4:16 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope you had a great holiday! The client was wondering if we could have a conference call on this, this week or next. Please advise.

Thanks much – Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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From: Berger, Tom C.
Sent: Tuesday, December 10, 2019 2:10 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just checking back in – thanks - Tom

From: Berger, Tom C.
Sent: Thursday, December 5, 2019 9:46 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

When we spoke before Thanksgiving (I hope you had a great one!) you indicated that the reports were being reviewed and that I should reach out to you in early December.

Is there any update?

Thanks much and best regards – Tom

Thomas C. Berger
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From: Berger, Tom C.
Sent: Monday, November 18, 2019 1:17 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

The PMN submitter asked me to reach out to you to see if we can schedule a conference call (including EPA, K&H, and the submitter) on this case re status and pathforward.

Thanks - Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Friday, March 29, 2019 5:43 PM
To: Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom,
I set the meeting up for Wednesday April 3, at 11 am. RAD has accepted the invitation for that time.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

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1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Bauer, Jeff
Sent: Tuesday, March 26, 2019 11:37 AM
To: 'Berger, Tom C.' <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom, I left you a voice message, I am seeing what time it best for RAD to be part of the call.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

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1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Tuesday, March 26, 2019 11:30 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi folks –

Just thought I would check in with you on this.

Thanks again - Tom

From: Berger, Tom C.

Sent: Friday, March 22, 2019 2:12 PM

To: 'Bauer.jeff@Epa.gov' <Bauer.jeff@Epa.gov>; 'Schweer, Greg' <Schweer.Greg@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: **Ex. 4 CBI**

Hi folks –

I hope you are doing well. Jeff – this is the PMN case that my colleague, Dr. Rhys Daniels, spoke with you about earlier this week.

The issue is development of data needed to amend the existing section 5(e) order for this substance to add an additional use, and EPA approval of protocols for same. Would the Agency be available for a short conference call on this on one of the following days?:

- March 27 (except 12-2 ET)
- April 2
- April 3
- April 4

This is becoming more urgent from a commercial standpoint.

Thanks much - Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com

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Message

From: Berger, Tom C. [Berger@khlaw.com]
Sent: 5/13/2020 4:53:29 PM
To: Bauer, Jeff [Bauer.Jeff@epa.gov]
CC: Price, Amanda [price@khlaw.com]; Schweer, Greg [Schweer.Greg@epa.gov]; Daniels, Rhys G. [daniels@khlaw.com]
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just seeing if it makes sense to set up a conference call in a week or two.

Thanks much again - Tom

From: Berger, Tom C.
Sent: Friday, May 8, 2020 11:14 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Jeff/Greg – thanks again.

Can/should we schedule a conference call with the submitter in a week or two?

Happy Friday!

Tom

From: Berger, Tom C.
Sent: Thursday, May 7, 2020 4:17 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: Re: **Ex. 4 CBI**

Jeff - thanks much.

Tom

On May 7, 2020, at 4:03 PM, Bauer, Jeff <Bauer.Jeff@epa.gov> wrote:

Tom, I hope you hanging in there as well, I have an email out to see if I can get a status update on the Assessor and to address you questions sent into CDX for a meeting.

Jeff

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)

New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

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1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Thursday, May 07, 2020 1:57 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff – Just touching base as the submitter has requested a status update.

Thanks again - Tom

From: Berger, Tom C.
Sent: Tuesday, May 5, 2020 11:56 AM
To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; 'Schweer, Greg' <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff – Just checking in on this – thanks - Tom

From: Berger, Tom C.
Sent: Wednesday, April 29, 2020 11:12 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I just thought I would check in on this and see if the Agency needs any additional information.

Thanks again and best regards,
Tom

Thomas C. Berger
Partner
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From: Berger, Tom C.

Sent: Thursday, April 23, 2020 7:13 PM

To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Jeff - thanks much.

Your recent voicemail and follow-up email indicated that the EPA Chemist has evaluated the study" on **Ex. 4 CBI**, but that the reviewer did have a few questions and comments:

Ex. 4 CBI

Ex. 4 CBI

Ex. 4 CBI

To specifically answer the Chemist's questions:

Ex. 4 CBI

Ex. 4 CBI

* * *

We trust that you find this information useful in resolved all outstanding issues. As always, if you have any questions please do not hesitate to contact us.

Best regards,
Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Tuesday, April 21, 2020 5:17 PM
To: Daniels, Rhys G. <daniels@khlaw.com>; Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: **Ex. 4 CBI**

I am moving forward with the review based on the information I have on the two studies, I wanted to share with you her comments on the test. **Ex. 4 CBI**

Ex. 4 CBI	RAD has the
information and I am trying to get them to do the risk assessment based on	Ex. 4 CBI

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

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Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Daniels, Rhys G. <daniels@khlaw.com>
Sent: Tuesday, April 21, 2020 4:58 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: Ex. 4 CBI

Jeff,

As always, we hope that all is well.

Per your recent voicemail and follow-up email concerning the Ex. 4 CBI case, we understand that the chemist has two questions Ex. 4 CBI

Ex. 4 CBI

Thanks in advance for your response.

Rhys G. Daniels, Ph.D.
Staff Scientist
tel: +1 202.434.4270 | fax: +1 202.434.4646 | daniels@khlaw.com
1001 G Street NW, Suite 500 West | Washington, DC 20001

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Thursday, April 16, 2020 1:02 PM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: Ex. 4 CBI

Tom,

The chemist sent me a memo Ex. 4 CBI and they had two questions, I called and left you a message today Ex. 4 CBI I sent RAD a request last week to update the HH assessment Ex. 4 CBI as in my April 4, 2020 email to you. I have two emails into RAD on this case and will try an update you again in a week or

so. I requested RAD set up a date with me to have a meeting to discuss how to proceed with this PMN.

Thanks
Jeff

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
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From: Berger, Tom C. <Berger@khlaw.com>
Sent: Thursday, April 16, 2020 12:28 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope that all is well.

Just checking in re status update. A non-CBI-containing email from you would probably be the best (if needed at some later time we can use EPA's new CBI via email authorization form if the submitter agrees).

Thanks again – Tom

From: Berger, Tom C.
Sent: Wednesday, April 8, 2020 11:06 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Jeff – thanks much for the update. Hope you and all at EPA are staying safe.

Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, April 8, 2020 11:03 AM
To: Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom,

Ex. 4 CBI

I will follow up with you next wed with a status update.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

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1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Wednesday, April 08, 2020 10:48 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Greg –

I was just going through my to-do list and thought I would circle back on these two cases. I hope everyone is hanging in there.

Thanks again – Tom

From: Berger, Tom C.
Sent: Monday, March 30, 2020 3:46 PM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>; Price, Amanda <price@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Greg / all – completely understood – thank you so much.

Tom

From: Schweer, Greg <Schweer.Greg@epa.gov>
Sent: Monday, March 30, 2020 3:42 PM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Bauer, Jeff <Bauer.Jeff@epa.gov>
Subject: RE: **Ex. 4 CBI**

Hi Tom.

I am not ignoring you. I did check with Jeff Bauer early last week on this case. He filled me in on the requests he had made of RAD to review submitted test data and your request for a meeting. However, believe it or not, we have been having issues reliably being able to access our CBI-secure LAN. This hampers our ability to efficiently complete work. I will check on the status of your case as soon as I can.

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Monday, March 30, 2020 11:51 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: Ex. 4 CBI

Hi Greg –

Hope all is well.

Just thought I would check in with you on the Ex. 4 CBI LVEA (Lauren Davis) and Ex. 4 CBI with Jeff Bauer.

Thanks all always - Tom

From: Berger, Tom C.
Sent: Tuesday, March 24, 2020 11:12 AM
To: Schweer, Greg <Schweer.Greg@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: Ex. 4 CBI

Greg – thanks so much as always. I also have an LVE with Lauren Davis Ex. 4 CBI held up in the process. Lauren has been responsive but the case has stalled (again, however, I understand the challenges you are facing).

These are my two “priority” cases.

Tom

From: Schweer, Greg <Schweer.Greg@epa.gov>
Sent: Tuesday, March 24, 2020 11:07 AM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: Re: Ex. 4 CBI

Tom,

Yes, things are a bit crazy. I will check into the case status today or tomorrow.

Sent from my iPhone

On Mar 24, 2020, at 10:48 AM, Berger, Tom C. <Berger@khlaw.com> wrote:

Hi Greg –

Obviously things are crazy and I don't want to push Jeff too hard but no response from Jeff on this case for a month.

Hang in there....

Tom

From: Berger, Tom C.
Sent: Monday, March 23, 2020 6:22 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies – just want to make sure you are getting these emails. Understand if there are delays.

Tom

From: Berger, Tom C.
Sent: Thursday, March 19, 2020 5:22 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff – checking in again – thanks - Tom

From: Berger, Tom C.
Sent: Monday, March 16, 2020 1:40 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I know things are crazy but checking in again – thanks - Tom

From: Berger, Tom C.
Sent: Wednesday, March 11, 2020 3:43 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Checking in again - thanks

From: Berger, Tom C.
Sent: Friday, March 6, 2020 1:33 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

The submitter is quite anxious – can we touch base next week?

Thanks much - Tom

From: Berger, Tom C.
Sent: Tuesday, February 25, 2020 9:08 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just checking in on this – thanks - Tom

From: Berger, Tom C.
Sent: Thursday, February 20, 2020 12:18 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope that all is well.

Per our discussions, the submitter has modified the questions to focus on toxicity/risk issues and submitted them via CDX yesterday. Can we start looking at conference call dates the week of March 9?

Thanks and best regards,
Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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From: Berger, Tom C.
Sent: Wednesday, January 29, 2020 11:41 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies we keep playing phone tag – can we discuss how to convert the below questions into questions that would be acceptable to RAD so we can schedule a call with you and RAD? Your voicemail suggested the below are more legal/regulatory than risk-based questions. We still need the below questions answered – perhaps we tee up the more scientific ones for RAD then have the call to address both types of questions. The submitter is under growing commercial pressure.

Thanks much again - Tom

From: Berger, Tom C.
Sent: Monday, January 20, 2020 3:50 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Apologies that we could not connect last week. Let's try to touch base tomorrow (Tuesday) if possible to discuss how to move this forward.

Thanks again – Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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From: Berger, Tom C.
Sent: Monday, January 13, 2020 2:50 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**
Importance: High

Hi Jeff –

Following is the list of questions we are considering submitting through CDX. Please let me know if these look ok.

Thanks again and best regards,
Tom

* * *

*(1) Based on review of the submitted physical-chemical properties test data, does EPA now agree that use of **Ex. 4 CBI** as described in the PMN poses no unreasonable risk of injury and so plans to revoke the consent order?*

(2) If so, what is the process for revoking the current consent order? Does the submitter now need to request that EPA revoke the order, or will EPA itself initiate revocation? What is the expected timing for revocation? How would EPA communicate such revocation?

(3) How would revocation of the consent order impact the final SNUR for the subject substance?

(4) Would a SNUN be a more expedient approach?

* * *

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Wednesday, January 8, 2020 8:56 AM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Tom, I am expecting information from the engineer today or tomorrow on the **Ex. 4 CBI** test. I left you a message. There is a new procedure for us to set up meeting with RAD. I am to have the submitter send in a list of questions for RAD, they will assign someone up there as a Lead person who has two weeks and will set a date for when we can have a meeting. This may be our best route to other than just me bugging them to get things done. There were a series of emails on this case last week but now everyone is back from the holidays I am trying to get this case moving again.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Tuesday, January 07, 2020 4:16 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I hope you had a great holiday! The client was wondering if we could have a conference call on this, this week or next. Please advise.

Thanks much – Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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From: Berger, Tom C.
Sent: Tuesday, December 10, 2019 2:10 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

Just checking back in – thanks - Tom

From: Berger, Tom C.
Sent: Thursday, December 5, 2019 9:46 AM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Daniels, Rhys G. <daniels@khlaw.com>
Subject: RE: **Ex. 4 CBI**

Hi Jeff –

When we spoke before Thanksgiving (I hope you had a great one!) you indicated that the reports were being reviewed and that I should reach out to you in early December.

Is there any update?

Thanks much and best regards – Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
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From: Berger, Tom C.

Sent: Monday, November 18, 2019 1:17 PM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

The PMN submitter asked me to reach out to you to see if we can schedule a conference call (including EPA, K&H, and the submitter) on this case re status and pathforward.

Thanks - Tom

From: Bauer, Jeff <Bauer.Jeff@epa.gov>

Sent: Friday, March 29, 2019 5:43 PM

To: Berger, Tom C. <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Tom,

I set the meeting up for Wednesday April 3, at 11 am. RAD has accepted the invitation for that time.

Jeff Bauer - Program Manager

United States Environmental Protection Agency (USEPA)

Office of Pollution Prevention and Toxics (OPPT)

New Chemicals Program (7405M)

<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M

1201 Constitution Ave., NW

Washington, DC 20004

Phone: 202-564-9042, Fax: 202-564-9490

From: Bauer, Jeff

Sent: Tuesday, March 26, 2019 11:37 AM

To: 'Berger, Tom C.' <Berger@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Tom, I left you a voice message, I am seeing what time it best for RAD to be part of the call.

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>

Sent: Tuesday, March 26, 2019 11:30 AM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Schweer, Greg <Schweer.Greg@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi folks –

Just thought I would check in with you on this.

Thanks again - Tom

From: Berger, Tom C.

Sent: Friday, March 22, 2019 2:12 PM

To: 'Bauer.jeff@Epa.gov' <Bauer.jeff@Epa.gov>; 'Schweer, Greg' <Schweer.Greg@epa.gov>

Cc: Daniels, Rhys G. <daniels@khlaw.com>

Subject: **Ex. 4 CBI**

Hi folks –

I hope you are doing well. Jeff – this is the PMN case that my colleague, Dr. Rhys Daniels, spoke with you about earlier this week.

The issue is development of data needed to amend the existing section 5(e) order for this substance to add an additional use, and EPA approval of protocols for same. Would the Agency be available for a short conference call on this on one of the following days?:

- March 27 (except 12-2 ET)
- April 2
- April 3
- April 4

This is becoming more urgent from a commercial standpoint.

Thanks much - Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com

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Message

From: Deaver, Noland [Deaver.Noland@epa.gov]
Sent: 5/12/2020 5:26:51 PM
To: Chen, Alice [Alice.Chen-1@dupont.com]
CC: Yan, James [Yan.James@epa.gov]; Sullivan, Andrew [sullivan.andrew@epa.gov]; Schweer, Greg [Schweer.Greg@epa.gov]
Subject: Agreement to authorize transmittal of TSCA CBI via Outlook email with designated Agency representatives during the modified working conditions due to COVID-19
Attachments: Authorization Form for CBI transmittal by e-mail revised 4-20.docx

Dear Alice:

In an effort to encourage social distancing and help reduce community spread of COVID-19, most EPA staff have been authorized to telework. With a majority of EPA staff now teleworking from remote sites, some minor changes to the normal TSCA section 5 review processes, including the TSCA section 5(a)(3) determination processes, are required. Specifically, the normal process by which section 5(a)(3)(C) determination documents, section 5(e) orders, and assessment reports are transmitted to submitters, because they contain information claimed as CBI, are hard copies submitted by the mail or courier services and via fax machines. These methods of delivery are not available from remote sites and therefore other means of transmitting this information must be utilized.

Given this extraordinary situation, and to avoid delay in addressing TSCA section 5 requirements, the Agency is offering an option to allowed affected persons to agree to allow EPA to transmit these materials via normal non-encrypted Outlook email. If you agree to this, the Agency will transmit these documents to you via email during the period in which a majority of EPA staff is teleworking. In the absence of this agreement EPA may need to extend the review period for your submission or issue a unilateral order under Section 5(e). Please note that EPA is not requiring companies to agree to transmission via email. Rather this communication explains the constraints we are acting under, and the delays that would result in the absence of email transmission. Companies are free to choose as appropriate.

Also, please note that agreeing to this process is a limited waiver of the TSCA CBI procedural protections, which generally restricts the transmission of CBI over a non-encrypted email system. That said, EPA's email system is compliant with all applicable Federal government information security provisions, including the Federal Information Security Management Act, and EPA's email systems meet the level of protection required for storing and transmitting CBI. Furthermore, your agreement will not constitute a waiver of substantive CBI protections, meaning that the information transmitted and claimed as confidential will only be disclosed consistent with TSCA, other applicable laws, and associated implementing regulations.

If you wish to grant EPA a limited waiver to transmit the materials via EPA's email system during the period in which a majority of EPA staff is teleworking, please have your authorized representative complete (e.g., add the case number), sign, and return the attached to Greg Schweer (Schweer.greg@epa.gov) as well as to any EPA staff who were cc'd on the email sent to you. If you have any questions about this communication or the described process, please contact Greg Schweer at (202) 564-8469 or the EPA Program Manager assigned to the case.

Sincerely,
Noland Ryan Deaver, M.S.
Environmental Protection Specialist
US Environmental Protection Agency, New Chemicals Management Branch
(202)564-3181

Agreement to authorize transmittal of TSCA Confidential Business Information (CBI) via Outlook email by designated Agency representatives during the period of EPA telework due to COVID-19

Documents concerning: PMN-XX-XXX

COMPANY authorizes EPA to transmit documents related to the above referenced TSCA submission, including information claimed as CBI, to **COMPANY** (or its technical contact listed on the PMN form) through EPA's Outlook email system. This authorization applies only during those periods where EPA staff working on PMN-XX-XXX are teleworking due to COVID-19 concerns and may be withdrawn at any time. Nothing in this authorization diminishes or otherwise limits **COMPANY'S** protections under TSCA to assert information as CBI, or otherwise authorizes the release of any information claimed as CBI without exhausting all provisions of TSCA protecting the release of such information. I have the authority to sign this on behalf of **COMPANY**

Signature of authorized person: _____

Name of authorized person printed or typed: _____

Title: _____

Email address: _____

Telephone number: _____

COMPANY _____

Message

From: Berger, Tom C. [Berger@khlaw.com]
Sent: 5/8/2020 3:14:09 PM
To: Bauer, Jeff [Bauer.Jeff@epa.gov]
CC: Price, Amanda [price@khlaw.com]; Schweer, Greg [Schweer.Greg@epa.gov]; Daniels, Rhys G. [daniels@khlaw.com]
Subject: RE: **Ex. 4 CBI**

Jeff/Greg – thanks again.

Can/should we schedule a conference call with the submitter in a week or two?

Happy Friday!

Tom

From: Berger, Tom C.
Sent: Thursday, May 7, 2020 4:17 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>
Subject: Re: **Ex. 4 CBI**

Jeff - thanks much.

Tom

On May 7, 2020, at 4:03 PM, Bauer, Jeff <Bauer.Jeff@epa.gov> wrote:

Tom, I hope you hanging in there as well, I have an email out to see if I can get a status update on the Assessor and to address you questions sent into CDX for a meeting.

Jeff

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

EPA East Building, room 4133M
1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Berger, Tom C. <Berger@khlaw.com>
Sent: Thursday, May 07, 2020 1:57 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G.

<daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff – Just touching base as the submitter has requested a status update.

Thanks again - Tom

From: Berger, Tom C.

Sent: Tuesday, May 5, 2020 11:56 AM

To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; 'Schweer, Greg' <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff – Just checking in on this – thanks - Tom

From: Berger, Tom C.

Sent: Wednesday, April 29, 2020 11:12 AM

To: Bauer, Jeff <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Hi Jeff –

I just thought I would check in on this and see if the Agency needs any additional information.

Thanks again and best regards,
Tom

Thomas C. Berger

Partner

tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com

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From: Berger, Tom C.

Sent: Thursday, April 23, 2020 7:13 PM

To: 'Bauer, Jeff' <Bauer.Jeff@epa.gov>

Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>; Daniels, Rhys G. <daniels@khlaw.com>

Subject: RE: **Ex. 4 CBI**

Jeff - thanks much.

Your recent voicemail and follow-up email indicated that the EPA Chemist has evaluated the study" on **Ex. 4 CBI** but that the reviewer did have a few questions and comments:

Ex. 4 CBI

Ex. 4 CBI

To specifically answer the Chemist's questions:

Ex. 4 CBI

Ex. 4 CBI

* * *

We trust that you find this information useful in resolved all outstanding issues. As always, if you have any questions please do not hesitate to contact us.

Best regards,
Tom

Thomas C. Berger
Partner
tel: 202.434.4285 | fax: 202.434.4646 | berger@khlaw.com
1001 G Street, N.W., Suite 500 West | Washington, D.C. 20001

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From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Tuesday, April 21, 2020 5:17 PM
To: Daniels, Rhys G. <daniels@khlaw.com>; Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: **Ex. 4 CBI**

I am moving forward with the review based on the information I have on the two studies, I wanted to share with you her comments on the test. **Ex. 4 CBI**

Ex. 4 CBI RAD has the
information and I am trying to get them to do the risk assessment based on **Ex. 4 CBI**

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchems/>

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1201 Constitution Ave., NW
Washington, DC 20004
Phone: 202-564-9042, Fax: 202-564-9490

From: Daniels, Rhys G. <daniels@khlaw.com>
Sent: Tuesday, April 21, 2020 4:58 PM
To: Bauer, Jeff <Bauer.Jeff@epa.gov>; Berger, Tom C. <Berger@khlaw.com>
Cc: Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: **Ex. 4 CBI**

Jeff,

As always, we hope that all is well.

Per your recent voicemail and follow-up email concerning the **Ex. 4 CBI** case, we understand that the chemist has two questions concerning **Ex. 4 CBI**

Ex. 4 CBI

Thanks in advance for your response.

Rhys G. Daniels, Ph.D.
Staff Scientist
tel: +1 202.434.4270 | fax: +1 202.434.4646 | daniels@khlaw.com
1001 G Street NW, Suite 500 West | Washington, DC 20001

From: Bauer, Jeff <Bauer.Jeff@epa.gov>
Sent: Thursday, April 16, 2020 1:02 PM
To: Berger, Tom C. <Berger@khlaw.com>
Cc: Daniels, Rhys G. <daniels@khlaw.com>; Price, Amanda <price@khlaw.com>; Schweer, Greg <Schweer.Greg@epa.gov>
Subject: RE: **Ex. 4 CBI**

Tom,

The chemist sent me a memo (**Ex. 4 CBI**) and they had two questions, I called and left you a message today (**Ex. 4 CBI**). I sent RAD a request last week to update the HH assessment (**Ex. 4 CBI**) as in my April 4, 2020 email to you. I have two emails into RAD on this case and will try an update you again in a week or so. I requested RAD set up a date with me to have a meeting to discuss how to proceed with this PMN.

Thanks
Jeff

Jeff Bauer - Program Manager
United States Environmental Protection Agency (USEPA)
Office of Pollution Prevention and Toxics (OPPT)
New Chemicals Program (7405M)
<http://www.epa.gov/oppt/newchemicals/>

EPA East Building, room 4133M